



Arent Fox

Chemical & Life Sciences

Year in Review 2017

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Introduction

This year brought us very significant changes in patent jurisprudence from the Supreme Court and Federal Circuit affecting the Chemical & Life Sciences patent practice.

The Supreme Court decided five patent cases in 2017, upending decades of Federal Circuit precedent. The Court expanded patent exhaustion doctrine, limited venue for patent litigation, and eliminated the defense of laches. The Court also limited infringement under 271(f), excluding from infringement those situations where only one component of a multicomponent system is exported from the United States. The Court also resolved key issues in implementing the Biologics Price Competition and Innovation Act (“BPCIA”). Notably, each of these decisions reversed the Federal Circuit in nearly unanimous decisions.

The Federal Circuit in 2017 decided *Aqua Products en banc*, reversing the Patent Trial & Appeal Board (“Board”) for placing the burden on patent owners with respect to a motion to amend in IPR. Although this may sound like a groundbreaking victory for patent owners, the effect of this decision may not be as widespread. In addition, several other cases were argued in 2017 dealing with other aspects of IPR, including the constitutionality of the procedure itself.

The Federal Circuit continued the trend of invalidating diagnostic patent claims under 35 U.S.C. § 101, often at the motion to dismiss stage of litigation. In *Cleveland Clinic*, the Federal Circuit found the patent owner’s claims to detecting myeloperoxidase (MPO) in a patient’s blood and correlating the results to cardiovascular risk is directed to ineligible subject matter. With respect to on-sale bar, the Federal Circuit in *Helsinn* invalidated patents over an on-sale bar due to a contract for sale more than one year before the filing of its patents. The court held the invention was ready for patenting at the time of the contract, and the America Invents Act (“AIA”) did not change the meaning of “on sale” in the circumstances presented.

The Federal Circuit issued several decisions upholding claims over obviousness challenges. These cases show some emerging trends in the area of obviousness. First, it is difficult to rely on inherency in order to establish that a claim is obvious. Second, the Federal Circuit places more emphasis on “reasonable expectation of success”

than in the past. Third, disagreement among the judges has arisen as to how to weigh the *Graham* factors.

The written description case law relating to antibodies took a significant turn in 2017 with the Federal Circuit’s decision in *Amgen v. Sanofi*. There, the court rejected the “newly characterized antigen” test which, according to the Court, “flouts the basic legal principles of the written description requirement.” The court also condoned the use of post-filing date examples to show the specification does not disclose sufficient species to provide written description support for the full breadth of the claims.

The Federal Circuit’s approach on indefiniteness and joint-infringement appears favorable for patent owners. The court showed that it is willing to look hard at claim scope before throwing in the towel and finding invalidity for indefiniteness. The court upheld joint infringement for pharmaceutical co-administration claims, showing the viability of joint infringement in the pharmaceutical field under the framework of *Akamai*.

On doctrine of equivalents (DOE) in the chemical arts and inequitable conduct, the court issued decisions unfavorable for patent owners. The court suggested that the function-way-result (FWR) test does not apply in chemical arts, but instead that the “insubstantial differences” test “might seemingly be more appropriate.” This will often make proving DOE more difficult in the chemical arts. As to inequitable conduct, the Federal Circuit took the unprecedented approach of relying on litigation misconduct to make an adverse inference of deceptive intent for inequitable conduct in prosecuting the patents before the Patent Office.

At the Supreme Court

Impression Products. v. Lexmark International, 137 S. Ct. 1523 (2017)

The Supreme Court in *Impression Prods. v. Lexmark Int'l*, 137 S. Ct. 1523 (2017) (vote 7–1) drastically altered the landscape of patent exhaustion that had been established over the past 30 years by the Federal Circuit. The doctrine of patent exhaustion stipulates that the patent right in a particular item is exhausted once the patentee or its licensee first sells the item, and thereafter the patent owner or licensee has no ability to sue downstream purchasers of the item for patent infringement. The Federal Circuit’s jurisprudence had established two exemptions limiting patent exhaustion:

1. **Conditional Sale Doctrine:** When a patent owner or its licensee places contractual limitation on a product when its sold, the later violation of those limitations may give rise to patent infringement against downstream purchasers. See *Mallinckrodt, Inc. v. Medipart, Inc.*,¹ and
2. **Territorial Patent Exhaustion:** When a patent owner or its licensee first sells a product abroad, those sales do not exhaust any U.S. patent rights in those products. See *Jazz Photo Corp. v. International Trade Commission*.²

The Supreme Court, on review, analyzed its own cases predating the Federal Circuit rulings and concluded that those cases compelled it to overrule the appeals court. In doing so, the Court removed the Federal Circuit’s restrictions on the scope of patent exhaustion and exposed patent owners to increased risk of competitive threat from those who refurbish their products.

Lexmark sold printer cartridges domestically at a discount under its “Return Program” or at full price with no restrictions on subsequent use. Under the Return Program, customers who bought printer cartridges were contractually obliged to return spent cartridges only to

authorized Lexmark facilities. Lexmark also sold printer cartridges outside the United States. Impression obtained spent Lexmark printer cartridges and refurbished and refilled them, then they sold them at a discount in competition with Lexmark printer cartridges. The Federal Circuit sitting *en banc* held that the above two exemptions to the patent exhaustion doctrine allowed Lexmark to maintain a patent infringement action despite the prior domestic and foreign sales of its cartridges.

[The Supreme] Court ... has long held that, even when a patentee sells an item under an express restriction, the patentee does not retain patent rights in that product.

The Supreme Court reversed, finding exhaustion for all cartridges whether sold domestically or abroad. The Court found that the Federal Circuit had understated the historical antipathy toward restraints on alienation. The Court also pointed to several of its earlier decisions holding that “even when a patentee sells an item under an express restriction, the patentee does not retain patent rights in that product.” *Id.* at 1532–33. The Court cited a long line of precedent up to and including its recent decision in *Quanta Computer, Inc. v. LG Electronics, Inc.*³ making clear that a patentee or its licensee exhausted all patent rights upon sale of the item.

The Court found fault with the Federal Circuit’s view that the “patentee does not have to hand over the full ‘bundle of rights’ every time” a product is sold, thereby implying that a patentee could restrict subsequent sales. *Id.* at 1533–34. The Court noted the misstep in this logic is that the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on “the scope of the patentee’s rights.” *Id.* Viewed in this context, after a sale the patentee’s right to exclude is extinguished. The Court noted that this does not mean that a patentee cannot place restrictions on a licensee.

The Court explained that a patentee may place restrictions on a licensee that are enforceable through the patent law although exhaustion works independently of these restrictions:

1 *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F. 2d 700, 721 (Fed. Cir. 1992) (a patentee may sell an item and retain the right to enforce, through patent infringement lawsuits, “clearly communicated, . . . lawful restriction[s] as to post-sale use or resale.”).

2 *Jazz Photo Corp. v. Int’l Trade Comm.*, 264 F. 3d 1094 (Fed. Cir. 2001) (a patentee’s decision to sell a product abroad did not terminate its ability to bring an infringement suit against a buyer that “import[ed] the article and [sold] . . . it in the United States.”).

3 *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U. S. 617, 638 (2008).



A patentee’s authority to limit *licensees* does not, as the Federal Circuit thought, mean that patentees can use licenses to impose post-sale restrictions on *purchasers* that are enforceable through the patent laws. So long as a licensee complies with the license when selling an item, the patentee has, in effect, authorized the sale. That licensee’s sale is treated, for purposes of patent exhaustion, as if the patentee made the sale itself.

Id. at 1534–35 (emphasis original). Where a purchaser violates a restriction on an authorized sale, the sole remedy is through contract action. The Court noted one exception where a licensee knowingly violates the terms of a license and a purchaser is aware of the breach, the sale is treated as if it never occurred.⁴ In this case, the patentee may sue the licensee and the purchaser who participated in the patent infringement.⁵

Patent exhaustion . . . has its roots in the antipathy toward restraints on alienation, . . . and nothing in the text or history of the Patent Act shows that Congress intended to confine that borderless common law principle to domestic sales.

Turning to the cartridges acquired abroad, the Supreme Court noted that the common law’s prohibition on restraints on alienation is “what helped tip the scales for global exhaustion” for copyrights in *Kirtsaeng*.⁶ The Court thus found that “[a]pplying patent exhaustion to foreign sales is just as straightforward.” *Id.* at 1536. Justice Ginsburg dissented, agreeing with the Federal Circuit that the territorial limit on patent rights also limits exhaustion. But the majority believed that “[e]xhaustion is a separate limit on the patent grant” and the fact that a patentee may be able to command a different price in the U.S. market has no bearing on the exhaustion issue. *Id.* at 1537.

The Court distinguished *Boesch v. Gräff*⁷ the single case dealing with international patent exhaustion:

Our decision did not, as Lexmark contends, exempt all foreign sales from patent exhaustion. . . . Rather, it reaffirmed the basic premise that only the patentee can decide whether to make a sale that exhausts its patent rights in an item.

In *Boesch*, the U.S. patentee had not authorized sales made by the German manufacturer who owned the corresponding German patent. Finally, the Court rejected the government’s “middle ground” approach that would allow patentees to place limits on foreign exhaustion. In doing so, the Court noted that “more is at stake than the dealings of the parties” and “[a]llowing patent rights to stick remora-like to that item as it flows through the market would violate the principle against restraints on alienation.” *Id.* at 1538.

The *Lexmark* opinion avoided addressing the repair / reconstruction dichotomy – a longstanding limitation on patent exhaustion. The repeated use of “refurbished” cartridges in its opinion suggests a view of Impression’s activities as a legitimate repair rather than illicit reconstruction of the patented article. Where a patented item is sold and then used to reconstruct an infringing device, patent exhaustion does not reach the reconstructed device. In *American Cotton Tie Co. v. Simmons*,⁸ the Supreme Court allowed an infringement action to proceed where a patented buckle and strap device used to hold cotton together was being reconstructed by the accused infringer. In normal use, the cotton tie was cut to release the cotton and the used metal parts were sold for scrap. The defendant purchased the used devices, reattached the straps, and resold them for use in the same manner as the patentee. The patent exhaustion doctrine did not reach the reconstructed ties. One might distinguish this situation from *Lexmark* on the grounds that ink—an unpatented component—is what restored value to the refurbished cartridges.

4 *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U. S. 124, 127 (1938).

5 Under *General Talking Pictures Corp. v. Western Elec. Co.*, where a licensee “knowingly ma[de] . . . sales . . . outside the scope of its license,” the sale would be treated for purposes of exhaustion “as if no license whatsoever had been granted” by the patentee, and “the patentee could sue both the licensee and the purchaser—who knew about the breach—for infringement.”

6 *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519 (2013).

7 *Boesch v. Gräff*, 133 U.S. 697 (1890).

8 *American Cotton Tie Co. v. Simmons*, 106 U.S. 80 (1892).

The Court's silence on single-use restrictions for self-replicating technology is curious given its recent decision upholding those restrictions in *Bowman v. Monsanto*.⁹ Genetically modified seeds are sold to farmers with single-use restrictions that prohibit the farmers from replanting progeny seed. On its face, Monsanto's single-use restriction appears to be an impermissible attempt to limit the activity of a purchaser under *Impression Products v. Lexmark*. But the Supreme Court's focus on the item sold underscores that patent exhaustion does not extend to self-replicating technologies. Progeny seed are never actually sold by the patentee. Each progeny seed is a new item produced by the farmer and thus outside the view of the patent exhaustion doctrine.

Aside from illicitly reconstructed articles and self-replicating technologies, the patent exhaustion doctrine has regained life under *Impression Products v. Lexmark*, placing much downstream activity outside the reach of patent owners and their licensees.

Life Technologies Corp. v. Promega Corp., 137 S. Ct. 734 (2017)

After *Life Tech. v. Promega*, 137 S. Ct. 734 (2017) (vote 7–0), we now know that an accused infringer must export *more than one* component of a multicomponent system from the United States in order to infringe under §271(f)(1). While this holding seems formalistic, it is so by design. The Court based its decision not on policy but on the interpretation of the statute's "a substantial portion of" language:

Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the U.S. in a manner that would infringe the patent if such combination occurred within the U.S., shall be liable as an infringer.

35 U.S.C. § 271(f)(1) (emphasis added).

Promega's patent claim required five components, including: (1) a mixture of primers that mark the part of the DNA strand to be copied; (2) nucleotides for forming replicated

strands of DNA; (3) an enzyme known as *Taq* polymerase; (4) a buffer solution for the amplification; and (5) control DNA. LifeTech manufactured a *Taq* polymerase in the United States and shipped that component to the United Kingdom where it was assembled into kits used for polymerase chain reaction (PCR), a now-standard laboratory technique for amplifying DNA. The PCR kits LifeTech assembled abroad included all of the claimed components of Promega's patent.

LifeTech argued that because it supplied only the *Taq* polymerase—a single component—from the United States there could be no infringement under § 271(f)(1) because a single component of a combination could never amount to "a substantial portion of" the patented multi-component invention. The Federal Circuit had rejected this argument focusing on the significance of the *Taq* component itself. Indeed, the *Taq* polymerase was a required component for operability of the genetic testing kit recited in the claim, and LifeTech's own witness admitted that the *Taq* polymerase is one of the "main" and "major" components of the accused kits.

The Supreme Court reversed. First, the Court determined that "a substantial portion" of the components of a patented invention refers to a quantitative not qualitative measurement. Both "all" and "portion" convey a quantitative meaning. "All" means the entire quantity, without reference to relative importance. The phrase "of the components of a patented invention" modifies "substantial portion." A qualitative reading would render the phrase "of the components" unnecessary in the Court's view.

Having determined that the term "substantial portion" refers to a quantitative measurement, we must next decide whether, as a matter of law, a single component can ever constitute a "substantial portion" so as to trigger liability under § 271(f)(1). The answer is no.

Second, the Court concluded a single component can never constitute "a substantial portion" based on the text, context, and structure of the statute:

Taken alone, §271(f)(1)'s reference to "components" might plausibly be read to encompass "component" in the singular. . . . But §271(f)'s text, context, and structure leave us to conclude that when Congress said "components," plural, it meant plural, and when it said "component," singular, it meant singular.

9 *Bowman v. Monsanto Co.*, 133 S.Ct. 1761 (2013).

Id. at 742. Accordingly, the Court reversed the Federal Circuit and remanded.¹⁰

While the Court’s ruling sets forth a bright line rule for single component exports to construct a multi-component invention, it may have limited impact and says nothing when the exported item to be assembled abroad has more than one claimed component.

SCA Hygiene Prods. v. First Quality Baby Prods., 137 S. Ct. 954 (2017)

The Supreme Court in *SCA Hygiene Prods. v. First Quality Baby Prods.*, 137 S. Ct. 954 (2017) (vote 7–1) reviewed whether a defense of laches could be raised for a patent lawsuit filed within the six-year statutory limit for obtaining patent damages. “Laches is ‘a defense developed by the courts of equity’ to protect defendants against ‘unreasonable, prejudicial delay’ in filing a lawsuit.” *Id.* at 960. The Federal Circuit cited its patent-specific rule that laches was available even though the lawsuit was filed within the six-year statute of limitations of 35 U.S.C. § 262. The patent owner, SCA, disputed this citing several non-patent Supreme Court cases holding that laches could not be maintained where Congress had enacted a statute of limitations.

The Court reversed, essentially telling the Federal Circuit that there is nothing special about patent law:

The Federal Circuit and First Quality dismiss the significance of this Court’s many reiterations of the general rule because they were not made in patent cases. But as the dissenters below noted, “[p]atent law is governed by the same common-law principles, methods of statutory interpretation, and procedural rules as other areas of civil litigation.”

Id. at 964. The Court also pointed to its recent copyright case holding that “laches cannot defeat a damages claim brought within the period prescribed by the Copyright Act’s statute of limitations.” *Id.* at 960. Thus, under similar circumstances where a statute of limitations exists, the

Supreme Court had limited laches as a defense.

The Supreme Court also noted the redundancy of laches when a statute of limitation exists, noting the judicially developed laches and legislatively enacted statutes of limitation serve a similar function. Moreover, “[t]he enactment of a statute of limitations necessarily reflects a congressional decision that the timeliness of covered claims is better judged on the basis of a generally hard and fast rule rather than the sort of case-specific judicial determination that occurs when a laches defense is asserted.” *Id.* at 960. Given similar language in the respective statutes of limitation for patent and copyrights, the Court extended its earlier copyright holding to patent law. Thus, the defense of laches is unavailable due to the already existing six-year statute of limitations.

The Court, however, declined to comment on the defense of equitable estoppel despite there being a live controversy over whether SCA was equitably estopped from suing First Quality. Unlike laches, equitable estoppel requires that the patentee take some action that induces the defendant to infringe the patent:¹¹

Equitable estoppel may only arise when an accused infringer shows by a preponderance of evidence that (1) a patentee, acting on the basis of accurate facts, communicated something in a misleading way, by words, conduct, or omission, to an alleged infringer, (2) on which the accused infringer relied, (3) such that he would be materially prejudiced if the patentee is allowed to assert a claim that is inconsistent with his earlier communication.

In this case the patent owner SCA sent First Quality a letter alleging infringement. First Quality responded that its own earlier filed patent invalidated SCA’s patent. After some additional exchanges, the correspondence simply concluded. The Federal Circuit reversed the district court decision granting summary judgment of equitable estoppel because there were genuine issues of whether SCA’s could be seen as misleading First Quality to infringe. The Supreme Court having removed the laches issue allows

¹⁰ On remand, the Federal Circuit denied Promega’s request for a new trial to pursue damages for infringement limited to the United States. The court noted that Promega pursued an “all-or-nothing damages strategy” throughout the litigation, and waived its ability to assert another damages theory limited to infringement within the United States. *See Promega v. Life Techs.*, Case No. 2013-1011 (Fed. Cir. Nov. 13, 2017).

¹¹ *SCA Hygiene Prods. v. First Quality Baby Prods.*, 767 F.3d 1339 (Fed. Cir. 2014).

the case to proceed and First Quality to raise equitable estoppel as a defense, demonstrating that equitable estoppel remains a viable defense in patent cases.

TC Heartland v. Kraft Food Grp., 137 S. Ct. 1514 (2017)

In *TC Heartland v. Kraft Food Grp.*, 137 S. Ct. 1514 (2017) (vote 8–0), the Supreme Court drastically altered where patent infringement cases may be brought. Since 1990, the Federal Circuit had been interpreting the patent venue statute, 28 U.S.C. § 1400(b), to apply the broad definition of corporate residence found in the general venue statute 28 U.S.C. § 1391(c) to domestic corporations. The Federal Circuit interpreted the relevant statutes such that domestic corporations could be sued “in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.” *Id.* at 1515.

The Supreme Court reversed, explaining that it had “definitively and unambiguously held that the word ‘reside[nce]’ in § 1400(b) has a particular meaning as applied to domestic corporations: It refers only to the State of incorporation.” *Id.* at 1520. The Court noted that Congress’ later enactment of § 1391 “does not contain any indication that Congress intended to alter the meaning of § 1400(b) as interpreted in *Fourco*.” *Id.* Accordingly, the Court held that domestic corporations can only be sued for patent infringement within their state of incorporation.

Sandoz, Inc. v. Amgen, Inc., 137 S. Ct. 1664 (2017)

The Supreme Court in *Sandoz v. Amgen*, 137 S. Ct. 1664 (2017) (vote 9–0) decided two key issues involving the operation of the Biologics Price Competition and Innovation Act (“BPCIA”). The BPCIA provides an abbreviated pathway for pursuing biosimilar applications through the filing of an abbreviated biologic license application (“aBLA”). The statute includes provisions often referred to as the “patent dance,” which involves an orderly exchange of patent information to help streamline patent litigation between the reference product sponsor and the biosimilar

applicant. Under this scheme, the biosimilar applicant discloses its aBLA to the patent owner, and the patent owner provides a list of infringement contentions.

The first question decided by the Supreme Court is whether the biosimilar applicant’s participation in the patent dance can be enforced by Federal injunction. The Court answered this question in the negative. *Id.* at 1675. But it remanded the case to the Federal Circuit to determine whether state law claims for unfair competition were preempted by the BPCIA. On December 14, 2017, the Federal Circuit decided that the BPCIA does preempt state law claims.¹² As a practical matter, this means that if the biosimilar applicant refuses to participate in the patent dance then the patent owner’s only recourse is to file a declaratory judgment action.

The second question decided by the Supreme Court was whether the biosimilar applicant could deliver the 180-day notice of commercial marketing prior to FDA approval jump starting market entry, or whether it had to wait until approval. The Federal Circuit had held that the 180-day notice could only be delivered after approval. The Supreme Court reversed on this question, thus speeding up the time in which a biosimilar can enter the market after receiving approval for their aBLA. *Id.* at 1687. While the Supreme Court’s holdings in *Amgen v. Sandoz* and the Federal Circuit’s holding on remand have answered basic questions on the operation of the BPCIA, significant questions still remain.¹³

Federal Circuit *En Banc* Decisions

Aqua Products, Inc. v. Matal, 872 F.3d 1290 (Fed. Cir. 2017) (*en banc*)

The Federal Circuit issued its decision in the long awaited *en banc* case *Aqua Products v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) (*en banc*), weighing in on the legality of the Board’s procedure for placing the burden of proof and persuasion on the patent owner for a motion to amend in *inter partes* review. The decision reversed the Board’s decision denying a motion to amend, holding that it was improper for the Board to place the burden on the patent owner in adjudicating the motion to amend. Those hoping for a

12 *Amgen v. Sandoz*, Case No. 15-1499 (Fed. Cir. Dec. 14, 2017)

13 For example, it remains unresolved whether a district judge can take into consideration the failure to participate in the “patent dance” in deciding whether to grant a preliminary injunction. Another unresolved question is whether a biosimilar applicant must wait until filing of its aBLA with the FDA before it can give notice of commercial marketing.

ruling that would create certainty for the future were left disappointed, however. The majority opinion seemingly acknowledged defeat in reaching a strong consensus, stating “very little said over the course of many pages that form the five opinions in this case has precedential weight.” *Id.* at 1327.

The Court appeared to leave an opening for the PTO to enact rules that would place the burden on patent owners in a motion to amend by couching its decision in terms of the absence of a rule requiring deference:

The only legal conclusions that support and define the judgment of the court are: (1) the PTO has not adopted a rule placing the burden of persuasion with respect to the patentability of amended claims on the patent owner that is entitled to deference; and (2) in the absence of anything that might be entitled deference, the PTO may not place that burden on the patentee.

Id. Whether the Patent Office will try to engage in formal rulemaking on the issue of burden of proof for motions to amend remain to be seen.

On November 21, 2017, however, David P. Ruschke the Chief Administrative Patent Judge issued “Guidance on Motions to Amend in view of *Aqua Products*” stating that “the Board will not place the burden of persuasion on a patent owner with respect to the patentability of substitute claims presented in a motion to amend.”¹⁴ The Notice emphasized that beyond the burden of proof issue “generally speaking, practice and procedure before the Board will not change.” Accordingly, for the time being patent owners will have a slightly better chance of prevailing on their motions to amend before the Board.

Subject Matter Eligibility §101

The Cleveland Clinic v. True Health Diagnostics, 859 F.3d 1352 (Fed. Cir. 2017)

In *Cleveland Clinic v. True Health Diag.*, 859 F.3d 1352 (Fed. Cir. 2017), the Federal Circuit affirmed a district court’s dismissal of Cleveland’s lawsuit against True Health Diagnostics, alleging infringement of inventions related to identifying

myeloperoxidase (MPO), a symptom of cardiovascular disease, in a patient’s blood. The court found three patents claiming methods of testing for MPO in a bodily sample were ineligible under 35 U.S.C. § 101. In addition, Cleveland failed to prove induced or contributory infringement of the remaining method for treatment. The Federal Circuit’s affirmance illustrates the dilemma that diagnostic innovators face in drafting a single patent claim that is both (1) patent eligible and (2) capable of being infringed.

Cleveland’s invention related to ways to “see” MPO based on correlations of various MPO data from a patient population with known healthy or cardiovascular disease states. Data from a patient was compared to known data to determine whether a patient presented a risk of cardiovascular disease. The testing claims included a comparison step and a wherein clause stating that the measured levels of MPO correlates to “the extent of the test subject’s risk of having atherosclerotic cardiovascular disease.” *Id.* at 1356. The method of treatment claim required administration of a lipid lowering agent based on levels of MPO detected using their techniques.

Unlike CellzDirect, the asserted claims of the testing patents are directed to the natural existence of MPO in a bodily sample and its correlation to cardiovascular risk rather than to “a new and useful laboratory technique” for detecting this relationship.

Under the two-step *Alice* framework for determining patent eligibility, the court first assessed whether “the claims are directed to ineligible subject matter, such as a law of nature.” *Id.* at 1360. The court found the first prong easily met stating “[t]he claims of the testing patent are directed to multistep methods for observing the law of natures that MPO correlates to cardiovascular disease.” *Id.* According to the court, “just like *Ariosa*, the method starts and ends with naturally occurring phenomena with no meaningful non-routine steps in between.” *Id.* at 1361. The court distinguished *Rapid Litigation Management v. CellzDirect*,¹⁵ which it said related to a “new and useful laboratory technique,” whereas “Cleveland Clinic has not created a new laboratory technique; rather, it uses well-known techniques to execute the claimed method.” *Id.*

Under “Alice step two, [the Court] examine[s] the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally

¹⁴ See https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf.

¹⁵ *Rapid Litigation Management v. CellzDirect*, 827 F.3d 1042 (Fed. Cir. 2016).

occurring phenomena into a patent-eligible application.” *Id.* With respect to the claimed “determining” steps, the court found Cleveland employs known techniques:

Cleveland Clinic does not purport to have invented colorimetric-based assay, flow cytometry, or ELISA, or any of the claimed methods to “see” MPO and its derivatives in bodily samples. Rather, the claims here instruct that MPO levels be detected or determined using any of these known techniques.

Id. at 1362. And with respect to the “comparing” step where MPO levels are compared to statistically derived control or predetermined values,” the court found “Cleveland Clinic does not purport to derive new statistical methods to arrive at the predetermined or control levels of MPO that would indicate a patient’s risk of cardiovascular disease.” *Id.*

With respect to the method of treatment claims requiring “administering a lipid lowering agent to the selected human patient,” the court found Cleveland could not prove either contributory or induced infringement. *Id.* at 1363–64. The court noted “Contributory infringement occurs if a party sells, or offers to sell, a material or apparatus for use in practicing a patented process” but “the only ‘material or apparatus’ that Cleveland Clinic claims True Health sells are lab reports documenting the results of True Health’s testing services.” *Id.* at 1363. Active inducement to infringe

requires “specific intent and action to induce infringement.” *Id.* at 1364. The court noted, however, “[i]t is undisputed that True Health does not sell or prescribe lipid lowering drugs to patients.” *Id.* And Cleveland alleges no facts that “suggest any connection between True Health and doctors that may prescribe lipid lowering drugs.” *Id.*

True Health did not challenge the method of treatment claims under 101, and thus the court did not opine on the eligibility of these claims. As we noted last year, in *Rapid Litigation Management*, the court, in *dicta*, explained that “methods of treating disease,” like “methods of producing things,” are patent eligible—a position that appeared contrary to district court and Board decisions, finding methods of treatment ineligible.¹⁶ In 2017, district courts and the Board continued to invalidate methods of treatment under 35 U.S.C. 101.¹⁷ We expect that the Federal Circuit will have an opportunity to address whether methods of treatment are patent eligible in 2018. The court’s *dicta* in *Rapid Litigation Management*, and its 2011 *Classen* decision¹⁸ suggest that methods of treatment are patent eligible. However, a post-*Mayo*¹⁹, precedential decision on this issue would help clarify the landscape.

The Federal Circuit’s *Cleveland Clinic* decision follows the court’s trend of invalidating diagnostic and personalized medicine patent claims seen in *Myriad*,²⁰ *Ambry*,²¹ *Ariosa*,²² and *Genetic Tech*.²³ The Patent Office also issued a report detailing the recent changes in 101 jurisprudence and

16 See <http://bit.ly/2o8Bce3>.

17 See, e.g., *Mallinckrodt Hospital Products IP Ltd., Praxair Dist., Inc.*, Case No. 15-170-GMS (Dist. Ct. Del. September 5, 2017); *Natural Alternatives Int’l, Inc. v. Allmax Nutrition, Inc.*, Case No.: 16-cv-01764-H-AGS, 2017 WL 2733923 (S.D. Cal. June 26, 2017); *Ex parte Chamberlain*, Appeal No. 2014-009849 (Bd. Pat. App. & Int. Jan. 20, 2017).

18 *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011) (“The claims of the ‘139 and ‘739 patents are directed to a method of lowering the risk of chronic immune-mediated disorder, including the physical step of immunization on the determined schedule. These claims are directed to a specific, tangible application...we conclude that the subject matter of these two patents traverses the coarse eligibility filter of § 101.”).

19 *Mayo Collaborative Services v. Prometheus, Inc.*, 566 U.S. 66 (2012).

20 *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303 (Fed. Cir. 2012).

21 *In re Brca1- and Brac2-Based Hereditary Cancer Test Patent Litigation*, 774 F.3d 755 (Fed. Cir. 2014).

22 *Ariosa v. Sequenom*, 809 F.3d 1282 (Fed. Cir. 2015) (*en banc* denied).

23 *Genetic Tech v. Merial*, 818 F.3d 1369 (Fed. Cir. 2016).

the interested public's largely negative opinion of the same.²⁴ In response to the continuing assault on these patents, three patent associations (IPO, AIPLA, and ABA) have proposed legislative fixes to 35 U.S.C. § 101. So far, none of these efforts have gained traction in Congress.

On-Sale Bar

Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356 (Fed. Cir. 2017)

The Federal Circuit in *Helsinn Healthcare v. Teva Pharm USA*, 855 F.3d 1356 (Fed. Cir. 2017) reversed a district court decision upholding Helsinn's patents over an asserted on-sale bar due to a contract for sale more than one year before the filing of its patents.²⁵ The Federal Circuit held the invention was ready for patenting at the time of the contract, and the America Invents Act ("AIA") did not change the meaning of "on sale" in the circumstances here.²⁶ The court examined alleged statutory ambiguity over whether the AIA's "otherwise available to the public" language means that all prior art must be available to the public, thereby excluding secret or non-informing uses or sales. *Id.* at 1367–70. The court held that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale." *Id.* at 1371. Although questions linger as to the prior art effect of a patent owner's secret uses and entirely secret sales.

Almost two years before applying for its patent, Helsinn and MGI Pharma, Inc. entered into a licensing agreement and supply and purchase agreement. The agreements were announced in joint press releases. The press releases disclosed the detailed terms of the transactions but did not disclose details of the specific dosing formulations covered by the agreements, including the 0.25 and 0.75 mg doses. More than one year before Helsinn filed its patent, its clinical data showed that "81% of patients

who received the 0.25 mg dose of palonosetron experienced relief from CINV for 24 hours." *Id.* at 1374.

Helsinn asserted four pre-AIA patents and one AIA patent against Teva. The court was required to address two questions (1) whether the pre-AIA patented inventions were "subject to a sale or offer for sale prior to the critical date"; and (2) "whether the AIA changes the meaning of the on-sale bar under 35 U.S.C. § 102 so that there was no qualifying sale" for the asserted AIA patent. *Id.* at 1367.

It has been implicit in our prior opinions that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar.

With respect to the pre-AIA patents, the court noted that in *Medicines Co. v. Hospira*²⁷ it "explained that the question must be 'analyzed under the law of contracts as generally understood' and 'must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'" *Id.* at 1364. The court found a commercial sale here:

[T]he Supply and Purchase Agreement bears all the hallmarks of a commercial contract for sale. It obligated MGI to purchase exclusively from Helsinn and obligated Helsinn to supply MGI's requirements of the 0.25 and 0.75 mg doses if approved by FDA.

Id. The court noted implicit in its prior cases, FDA or other regulatory approval is not required to trigger an on-sale bar. However, it had to acknowledge that "absence of FDA approval may be a relevant consideration depending upon the other circumstances surrounding a transaction relating to a pharmaceutical formulation." *Id.* at 1366.

²⁴ See https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf.

²⁵ On January 16, 2018, the Federal Circuit denied rehearing and rehearing *en banc*. In a concurring opinion, Judge O'Malley responded to "Helsinn's petition and various amici briefs . . . [that] mischaracterize certain aspects of our panel opinion and advance policy-based criticisms about aspects of the law that this court is not at liberty to change." She noted "the *particular* agreement at issue triggered the on sale bar, in part—but not exclusively—because it was made public" and that not "all supply-side arrangements for future sales will invalidate a later-filed patent."

²⁶ Only one of the four asserted patents were subject to the AIA (i.e., a patent issuing from an application filed on or after March 16, 2013).

²⁷ *Medicines Co. v. Hospira*, 827 F.3d 1363 (Fed. Cir. 2016).

We conclude that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale.

With respect to the AIA patent, the court noted that the parties disputed whether the AIA changed the law:

Teva and various amici assert that by reenacting the existing statutory term, “on sale,” Congress did not change the meaning of the on-sale bar or disturb settled law. Helsinn, the government, and other amici argue that the AIA changed the law by adding the “otherwise available to the public” phrase. They argue that the on-sale bar now does not encompass secret sales and requires that a sale make the invention available to the public in order to trigger application of the on-sale bar.

Id. at 1368. The court noted, however, that much of the argument for change related to floor statements by members of Congress made during enactment of the AIA and those “statements do not identify any sale cases that would be overturned by the amendments.” *Id.* at 1369. The court also noted that even if the AIA was understood to overturn caselaw regarding entirely secret sales, the sale involved in the present case was publicly disclosed and would not be affected.

Citing the “seminal Supreme Court decision in *Pennock*,” the court noted that “[r]equiring such disclosure [of the details of the invention] as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar.” *Id.* at 1369. Because part of the rationale for an on-sale bar is to penalize inventors who delay in filing their patent applications, finding no on-sale bar here would “give a premium to those who should be least prompt to communicate their discoveries.” *Id.* Accordingly, the court concluded “that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale.” *Id.* at 1371. The court left open for future cases to decide whether entirely secret sales or uses would be considered prior art under the AIA.

Anticipation/Obviousness

In re Stepan Co., 868 F.3d 1342 (Fed. Cir. 2017)

The Federal Circuit, *In re Stepan Co.*, 868 F.3d 1342 (Fed. Cir. 2017) reversed the Board’s decision that an agrochemical

formulation comprising a surfactant system with various components at specific weight ratios was obvious as being a product of “routine optimization.” The court concluded that the Patent Office failed to explain why a person of ordinary skill in the art would have arrived at the claimed invention through routine optimization. Since no such rationale was provided, the Board improperly shifted the burden to the applicant to rebut obviousness.

The claims recited an aqueous glyphosate salt-containing concentrate comprising, *inter alia*, a surfactant system comprising:

from about 10 to about 60 weight percent, based on the weight of the surfactant system, of one or more dialkoxylated alkylamines;

from about 5 to about 30 weight percent, based on the weight of the surfactant system, of one or more water miscible solubilizers; and

from about 30 to about 75 weight percent, based on the weight of the surfactant system, of one or more amine oxides;

wherein the concentrate has a cloud point above at least 70°C or no cloud point when the concentrate is heated to its boiling point.²⁸

Id. at 1345–46. The Examiner found the prior art reference Pallas taught the surfactant components, and, for the claimed ranges, concluded “it is routine optimization to select and adjust the surfactants to this range since Pallas teaches the surfactant component comprises any combination of surfactants.” *Id.* at 1345. The Examiner further contended that although Pallas does not teach a cloud point above 70°C, achieving this cloud point would be a matter of “optimizing the formulation” because Pallas teaches the ideal cloud point should be above 60°C. The Board agreed and “found Stepan failed to provide evidence that it would not have been routine optimization for a skilled artisan to select and adjust the claimed surfactants to achieve a cloud point above at least 70°C.” *Id.* at 1346.

The Board failed to explain why it would have been “routine optimization” to select and adjust the claimed surfactants and achieve a cloud point above at least 70°C.

²⁸ Surfactant systems with high (or no) cloud points (where solution never becomes cloudy) allow for quicker formulation of glyphosate concentrates and thus quicker delivery to the market.



On review, the Federal Circuit found that the Board did not adequately explain its rationale as to why adjusting the claimed surfactants to achieve the claimed cloud point above 70°C would have been routine:

Missing from the Board’s analysis is an explanation as to *why* it would have been routine optimization to arrive at the claimed invention. Similar to cases in which the Board found claimed inventions would have been ‘intuitive’ or ‘common sense,’ the Board must provide some rational underpinning explaining why a person of ordinary skill in the art would have arrived at the claimed invention through routine optimization. ... Absent some additional reasoning, the Board’s finding that a skilled artisan would have arrived at the claimed invention through routine optimization is insufficient to support a conclusion of obviousness.

Id. at 1346 (emphasis original). Further, the court noted that the Board failed to show a “reasonable expectation of success,” which requires “more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result.” *Id.* at 1347. Specifically, “[r]eciting [the prior art’s] teachings that ‘any combination’ of surfactants may be used and that a cloud point above 60°C is desired fails to illuminate why a skilled artisan would have selected the claimed combination of surfactants and reasonably expected a cloud point above at least 70°C.” *Id.*

Under these circumstances, the court found that it was improper for the Board to shift the burden to the applicant to show why the claimed invention was not the result of routine optimization. With respect to the claimed cloud point “it was the PTO’s—not Stepan’s—burden to show that achieving a cloud point above 70°C would have been obvious to a person of ordinary skill in the art.” *Id.* at 1348.

Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A., 865 F.3d 1348 (Fed. Cir. 2017)

In *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348 (Fed. Cir. 2017) the Federal Circuit vacated and remanded the PTAB’s decision that a refrigerant composition comprising a specific unsaturated hydrofluorocarbon (HFO-1234yf) and at least one polyalkylene glycol (“PAG”) lubricant exhibiting a specified viscosity range was obvious over a combination of references. The Board’s unpatentability decision hinged on its finding that an obvious combination of prior art compounds taught in separate references would have resulted in the same composition claimed,

and that this composition would have inherently had the claimed viscosity property. The Federal Circuit faulted the Patent Office for failing to consider whether the allegedly inherent property was an unexpected result. This case illustrates the difficulty of arguing inherency within the context of obviousness in unpredictable technologies.

Honeywell’s patent claims a heat transfer composition for use in an air conditioning system comprising:

- a. at least about 50% by weight of 1,1,1,2-tetrafluoropropene (HFO-1234yf) having no substantial acute toxicity; and
- b. at least one polyalkylene glycol lubricant in the form of a homopolymer or co-polymer consisting of 2 or more oxypropylene groups and having a viscosity of from about 10 to about 200 centistokes at about 37 °C.

Id. at 1351–52. The Examiner (*inter partes* reexam) rejected the claims as being obvious over Inagaki, which teaches HFO-1234yf, and secondary references that purportedly disclose the use of PAG lubricants with HFC refrigerants. Honeywell submitted evidence that HFO refrigerants and PAG lubricants were known to be unstable and thus there was no reason to combine HFO-1234yf and a PAG lubricant. Honeywell also submitted evidence of secondary considerations, including unexpected stability of HFO-1234yf in combination with PAG lubricants over other similar refrigerants combined with PAGs.

The Board affirmed Examiner’s rejections. The Board found that since Inagaki teaches that HFO-1234yf “do not have any problem with respect to their general characteristics (e.g., *compatibility with lubricants* . . .),” it would have been obvious to combine HFO-1234yf with “known lubricants” such as PAGs. *Id.* at 1352 (emphasis in original). Moreover, because PAGs were known lubricants, the Board concluded that one of ordinary skill motivated to use HFO-1234yf would have arrived at its combination with a PAG lubricant by mere routine testing.

The Board also found that the stability of HFO-1234yf with a PAG lubricant are “inherent properties of otherwise known refrigerant that could not confer patentable weight to claimed mixture.” *Id.* In doing so, the Board rejected Honeywell’s evidence of unexpected stability. The Board acknowledged that Honeywell’s evidence shows the unpredictability of “how various refrigerants would have reacted with various lubricants,” but found that other evidence shows that one of skill in the art “*would no more have expected failure* with respect to the stability of combining [HFOs] with PAG *than*

would have expected success.” *Id.* at 1353. Thus, the Board concluded that, “due to the ‘overall unpredictability as to stability in the art,’ one of ordinary skill would have arrived at the claimed combination by mere routine testing.” *Id.*

We have previously stated that the use of inherency in the context of obviousness must be carefully circumscribed because “[t]hat which may be inherent is not necessarily known” and that which is unknown cannot be obvious.

The Federal Circuit vacated and remanded the Board’s decision. First, the court concluded that the Board improperly relied on inherency. The court reiterated the limitations of inherency in the context of obviousness and that unexpected properties must be considered:

What is important regarding properties that may be inherent, but unknown, is whether they are unexpected. All properties of a composition are inherent in that composition, but unexpected properties may cause what may appear to be an obvious composition to be nonobvious.

Id. at 1354–55. Here, the Board erred as a matter of law because it dismissed properties of the claimed invention as merely inherent, without further consideration as to unpredictability and unexpectedness.

Second, the Board erred in dismissing Honeywell’s evidence of unpredictability when it stated that one of ordinary skill would no more have expected failure than success in combining the references. This “amounts to a finding that one of ordinary skill would *not* have had a reasonable expectation of success in combining HFO-1234yf with PAG lubricants, but then seemed to make a burden-shifting argument that Honeywell did not persuasively establish that one of ordinary skill would have expected *failure*.” *Id.* at 1355 (emphasis original). Thus, the Board apparently determined that, because stability was unpredictable, one of ordinary skill would have made no predictions, but rather that “routine testing” would have led to the claimed combination:

That is reverse reasoning. Unpredictability of results equates more with nonobviousness

rather than obviousness, whereas that which is predictable is more likely to be obvious. Thus, reasoning that one would no more have expected failure than success is not a valid ground for holding an invention to have been obvious.

Id. at 1356. Indeed, a patent owner does not need to show “that one of ordinary skill would have expected *failure*—rather, the patent owner need only establish that the results would have been *unexpected* to one of ordinary skill at the time of invention, or ‘much greater than would have been predicted.’” *Id.* (emphasis original)

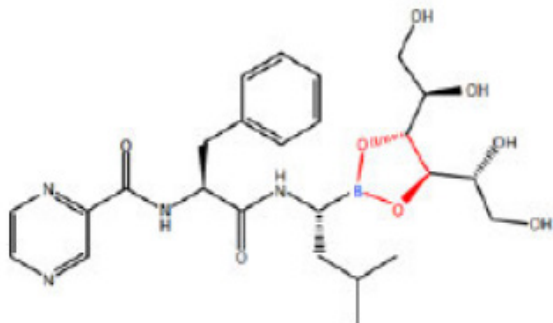
As a final matter, the court weighed in on the patentability of inventions made through “routine testing.” The last sentence of 35 U.S.C. § 103 provides that “[p]atentability shall not be negated by the manner in which the invention was made.” *Id.* According to the court, this was “enacted to ensure that routine experimentation does not necessarily preclude patentability.”²⁹

Millennium Pharms v. Sandoz, 862 F.3d 1356 (Fed. Cir. 2017)

In *Millennium Pharms. v. Sandoz*, 862 F.3d 1356 (Fed. Cir. 2017) the Federal Circuit reversed a district court decision invalidating as obvious Millennium’s patent for a lyophilized mannitol-containing prodrug that addressed stability problems of the active agent, Bortezomib. The district court determined the patented boronate ester of bortezomib was obvious since it inherently resulted from an obvious process—combining bortezomib with a known bulking agent (mannitol), and conducting a known process step (lyophilizing). In reversing, the Federal Circuit held that there was no teaching or suggestion to make the claimed compound nor was there a reasonable expectation the combination of references would solve bortezomib’s previously intractable stability problems. Moreover, the district court’s inherency analysis was erroneous because it improperly relied on hindsight.

29 See *In re Saether*, 492 F.2d 849, 854 (C.C.P.A. 1974) (“In his argument that ‘mere routine experimentation’ was involved in determining the optimized set of characteristics, the solicitor overlooks the last sentence of 35 U.S.C. § 103. . . Here we are concerned with the question of whether the claimed invention would have been obvious at the time it was made to a person having ordinary skill in the art—not how it was achieved.”); *In re Fay*, 347 F.2d 597, 602 (C.C.P.A. 1965) (“[W]e do not agree that ‘routine experimentation’ negatives patentability. The last sentence of section 103 states that ‘patentability shall not be negated by the manner in which the invention was made.’”).

The claimed compound is a boronate ester of bortezomib (a boronic acid) and D-mannitol (a hydroxy compound) having the structure below (highlight showing the bonds between the bortezomib and D-mannitol moieties).



Bortezomib was known as being efficacious against various cancers, but was never approved because of instability, rapid degradation in liquid formulations, and insolubility. The inventors developed the claimed compound after experimenting with many liquid formulations that failed, and then experimenting with lyophilized formulations (i.e., which are not intended to change the structure of the active ingredient). The claimed boronate ester of bortezomib acts as a prodrug that releases the active agent upon administration.

The parties agreed that bortezomib was the lead compound, and Sandoz argued that lyophilizing was known, bulking agents were known for use with lyophilizing, and mannitol was a known bulking agent. The district court held claims obvious because they were the inherent result of an allegedly obvious process – i.e., lyophilizing bortezomib in the presence of the bulking agent mannitol. The court stated that Millennium “conceded as a matter of law that the ester is the ‘natural result’ of freeze-drying bortezomib with mannitol.” *Id.* at 1363.

On appeal, the Federal Circuit framed the issue as “whether a person of ordinary skill, seeking to remedy the known instability and insolubility and to produce an efficacious formulation of bortezomib, would obviously produce the D-mannitol ester of bortezomib, a previously unknown compound.” *Id.* at 1364. The court answered this question in the negative and reversed the district court’s decision.

As an initial matter, the court noted the following regarding the teachings of the prior art:

- No reference shows or suggests ester formation at freeze-drying conditions, or that any such

ester might solve the problems of instability and insolubility. No reference provides a reason to make the mannitol ester of bortezomib.

- The prior art does not teach or suggest that lyophilizing of bortezomib in the presence of mannitol would form a new chemical compound, or provide a reason to make this specific new chemical compound, or that this new compound would solve the previously intractable problems of bortezomib formulation.
- Although mannitol was a known bulking agent, and lyophilizing was a known method of drug formulation, nothing on the record teaches or suggests that a person of ordinary skill should have used mannitol as part of a synthetic reaction to make an ester through lyophilizing.

Accordingly, because there was no teaching or suggestion to produce the claimed compound nor was there a reasonable expectation of success, the district court erred in its conclusion of obviousness.

[T]he inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.

The Federal Circuit also concluded that the district court erred in its inherency analysis as it relates to obviousness. The court noted that “[a] party must . . . meet a high standard in order to rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis.” *Id.* at 1367. Here, the district court’s analysis was tainted by hindsight since it relied on Millennium’s concession that the natural result of *its process* is the claimed invention. The Federal Circuit explained that the patentee’s path to the invention is not relevant, but rather what one of ordinary skill in the art would have done in view of the prior art. The district court’s approach ran counter to “[t]he last sentence of 35 U.S.C. § 103, [which] with great clarity, excludes such methodology in stating that ‘(p)atentability shall not be negated by the manner in which the invention was made.’” *Id.*

In *Honeywell* and *Millennium*, the Federal Circuit held that the lower tribunal’s inherent obviousness decision was

erroneous.³⁰ They follow the court's 2014 decision in *Par Pharm. v. TWi Pharms., Inc.*,³¹ where it articulated the "high standard" required to establish inherency in the context of obviousness. In *Par*, the court concluded that the claimed "no substantial difference" in food effect was not obvious because "[w]hile it *may* be true that a reduction in particle size naturally results in some improvement in the food effect," the defendant failed to show that "the reduction in particle size naturally results in 'no substantial difference' in the food effect."³² These cases show the Federal Circuit's reluctance to find inherency in the context of obviousness.

Cumberland Pharms. v. Mylan Institutional, 846 F.3d 1213 (Fed. Cir. 2017)

In *Cumberland Pharms. v. Mylan Institutional*, 846 F.3d 1213 (Fed. Cir. 2017) the Federal Circuit affirmed a district court holding of non-obviousness for Cumberland's patent claiming a chelating agent-free formulation of Acetadote® (intravenous acetylcysteine). The asserted prior art included the prior EDTA-containing Acetadote® product, an FDA document confirming Cumberland's commitment to study EDTA's role in product stability of Acetadote®, and Guilford, a reference describing an EDTA-free, low dose intravenous acetylcysteine for treating bioterror victims. The court found the FDA document did not provide motivation to remove EDTA without replacing it with another chelator, and Guilford lacked stability data for its much lower concentration product. This decision illustrates how the "reasonable expectation of success" prong of obviousness can bolster patents claiming stability-enhancing improvements where stability cannot be predicted.

Though not using the exact phrase, "reasonable expectation of success," the court thus found that the hypothetical relevant skilled artisan would not have reasonably expected a chelating-agent-free intravenous acetylcysteine formulation to succeed in being stable, a claim requirement.

The Federal Circuit reviewed the district court's findings with respect to "reasonable expectation of success"—a factual question—with deference. The court noted that "stability is an express claim requirement" and "[t]he reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Id.* at 1222. The district court found that at the time of the invention "persons of ordinary skill in the art would have assumed that EDTA, or some other chelating agent, was necessary to maintain stability in an acetylcysteine formulation." *Id.* On review, the Federal Circuit noted "[c]onsiderable evidence supports the finding that relevant skilled artisans believed that chelating agents were necessary to sequester metal contaminants and prevent oxidative degradation of acetylcysteine and that such artisans had no reasonable expectation of stability without such an agent." *Id.*

Mylan's evidence tended to show that "there is no need to chelate trace metal ions because degradation may be effectively avoided by an inert vial atmosphere together with modern manufacturing practices that leave very low levels of metal contaminants." But the court found that this data did not show a reasonable expectation of success at the time of the invention. Moreover, Guilford's teaching of an EDTA-free version of intravenous acetylcysteine did not cure the lack of reasonable expectation of success because "it also did not publish stability data." *Id.* at 1223. Evidence of record suggested that to the extent Guilford taught a stable formulation, there was evidence that "a person of ordinary skill would not expect it to remain stable as the concentration of acetylcysteine was raised to the level required by the '445 patent." *Id.*

Sanofi v. Watson Laboratories, 875 F.3d 636 (Fed. Cir. 2017)

In *Sanofi v. Watson Labs.*, 875 F.3d 636 (Fed. Cir. 2017) the Federal Circuit affirmed a district court decision

30 Similarly, in *Southwire Co. v. Cerro Wire LLC*, 870 F.3d 1306, 1310-11 (Fed. Cir. 2017), the court found that the Board erred in its obviousness determination, based on inherency, since it "cited no evidence that [the claimed] reduction of 30% in the pulling force would necessarily result from the claimed process." However, the Board's error was harmless "because, although it improperly invoked inherency, it need not have." *Id.* at 1311. Specifically, "[n]one of the patented steps differed in any material way from the prior art processes and "there is no evidence that the claimed 30% reduction in pulling force would have been unexpected or unattainable from the process disclosed in [the prior art]." *Id.* Therefore, the court affirmed the Board's obvious decision.

31 *Par Pharm. v. TWi Pharms., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014).

32 *Id.*



upholding a therapeutic method claim for Sanofi’s Multaq® (dronedarone). The patent was directed to decreasing a risk of cardiovascular hospitalization and claimed administering dronedarone to patients having several enumerated risk factors, which mirrored the patient population in Sanofi’s successful ATHENA clinical trial. Watson challenged the patent as obvious over Sanofi’s earlier clinical trials for dronedarone, which were directed to a different end-points and did not select for the same patient population. Sanofi pointed to these differences, as well as a failed clinical trial ANDROMEDA highlighting the drug’s potential dangers. This decision provides another example of how “reasonable expectation of success” can defeat an obviousness challenge to therapeutic method claims.

The method of treatment patent requires selection of patient population mirroring the criteria of Sanofi’s ATHENA clinical trial:

A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone . . . wherein said patient does not have severe heart failure . . . wherein said patient has a history of, or current, paroxysmal or persistent nonpermanent atrial fibrillation or flutter; and . . . wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:

- i. an age greater than or equal to 75; ii. hypertension; iii. diabetes; iv. a history of cerebral stroke or of systemic embolism; v. a left atrial diameter greater than or equal to 50 mm; and vi. a left ventricular ejection fraction less than 40%.

Id. at 642.

The asserted prior art include two prior clinical trials for dronedarone called EURIDIS/ADONIS, which “showed some positive results in the time to recurrence of atrial fibrillation and in ventricular rates, but they were not designed to investigate reduced hospitalization, let alone to do so for the patient population covered by the patent claims at issue.” *Id.* at 648. A post-hoc analysis of the EURIDIS/ADONIS study was published prior art that become a “centerpiece of the obviousness challenge in this case” stated:

Since it was shown that dronedarone is not only capable of maintaining [sinus rhythm] in many patients, but also of controlling heart rate in case of [atrial fibrillation] relapses, it is expected that treatment with this compound

will result in a significant reduction in the need of rehospitalization for cardiovascular reasons.

Id. at 642. Another study ANDROMEDA “showed the dangers of dronedarone severe enough to have spurred early termination of the study.” *Id.* at 648. Other studies present in the prior art “characterized the safety and efficacy data as confusing and severely challenged.” *Id.* The ATHENA clinical trial upon which the patent was based confirmed the “significant reduction in the need of rehospitalization” for patients with the claimed risk factors. *Id.*

Sanofi introduced significant evidence to challenge the contention that the post-hoc analysis statement of a “significant reduction in the need for rehospitalization” would have led to a “reasonable expectation of success” in support of an obviousness challenge. Its expert testified that the post-hoc study would have been “nothing more than a statement of hypothesis being tested in ATHENA” contradicting Watson and Sandoz’s expert statements that it was “a concrete assertion about what the authors expected.” *Id.* The court also heard evidence about the unreliability of post-hoc analyses generally, and heard testimony that one would have been especially skeptical in view of the failed ANDROMEDA clinical trial.

The court distinguished *PharmaStem*, where “expert testimony about prior-art references was rejected because the testimony could not ‘be reconciled with statements made by the inventors in the [patent] specification and with the prior art references themselves.’” *Id.* Interestingly, the Court’s opinion avoided common language used in invalidating claims for obviousness indicating that all that is needed is a “reasonable” expectation of success rather than “absolute predictability.” This case should be seen through the lens of appellate standard of review where the district court’s factual findings are given deference. The court indicated as much in concluding: “We conclude that the district court did not commit clear error in finding that a person of ordinary skill in the art ‘would have been at best cautiously optimistic that dronedarone could reduce the risk of cardiovascular hospitalization and hospitalization for AF in the ATHENA patient population’ and that Watson and Sandoz had failed to prove obviousness by clear and convincing evidence.” *Id.* at 650.

Mylan Institutional v. Aurobindo Pharma, 857 F.3d 858 (Fed. Cir. 2017)

In *Mylan Institutional v. Aurobindo Pharma*, 857 F.3d 858 (Fed. Cir. 2017) the Federal Circuit considered the validity of claims to a purified isosulfan blue (“ISB”), a dye used to

map lymph nodes. The court affirmed³³ the district court's preliminary injunction, finding that Aurobindo did not raise a substantial question of patent validity based on anticipation, obviousness, and indefiniteness. The patent claimed an ISB salt "having a purity of at least 99.0% by HPLC." The Federal Circuit's decision upholding the purified ISB claim demonstrates that where purification is a technical issue to be solved, patents to the purified product may provide a valuable scope of commercial protection.

Relevant to the purity issue, the market for ISB had been plagued for 30 years by supply disruptions and failed attempts to supply high purity ISB. In 1981, Hirsch Industries developed a 1% injectable solution of ISB, which it commercialized under the name Lymphazurin®. Coviden held the new drug application (NDA) for Lymphazurin and was the sole supplier of ISB for 30 years. Coviden was supplied by Sigma-Aldrich with ISB manufactured by Allied Chemical Corp. The ISB had unwanted lead impurities which were removed by Sigma's isolation process. In 2000, Allied stopped supplying Sigma with ISB, and Coviden was "forced to notify its customers that it was 'completely out of,' Lymphazurin®." *Id.* at 862. By 2008, Sigma had a new supplier (Innovassynth), which made ISB using ammonium dichromate, resulting in unwanted chromium impurities. Sigma in 2010 developed its own process for ISB. *Id.* at 863.

Mylan's predecessor Synerx Pharma LLC partnered with Apricore in 2004 to develop and market a generic version of Lymphazurin®. Apricore filed a patent application in 2007 that ultimately led to Mylan's purified ISB patent as well as process patents discussed *infra*, and an ANDA for Lymphazurin® that was approved in 2010. Mylan became the sole supplier of the 1% ISB drug product until 2016, when Aurobindo entered the market. *Id.*

Aurobindo argued that Mylan's purified ISB process was "anticipated by Sigma's ISB product because a Sigma Certificate of Analysis shows that Sigma made and sold ISB with a purity of 100% six years before." *Id.* at 870. The court found, however, that the "Sigma Certificate of Analysis related to a compound named 'Patent Violet Blue' and it was not clear that, at the time of the issuance of the Certificate, Sigma used that term to refer to ISB." *Id.* Moreover, other Sigma documents contradicted the document relied upon. Accordingly, the Federal Circuit rejected Aurobindo's anticipation argument and affirmed the district court's judgment on lack of anticipation.

We have previously acknowledged that "a purified compound is not always prima facie obvious over the [prior art] mixture" if the process to arrive at the purified compound is itself of patentable weight.

With respect to obviousness, the district court held that Aurobindo failed to raise a substantial question on motivation to combine or reasonable expectation of success. Further, the "court found that Apricore's process leading to the claimed ISB product with a purity of greater than 99.0% constituted 'an invention of patentable weight itself' and thus that the '050 patent claims would not necessarily have been prima facie obvious over the prior art mixture of (less pure) ISB and 'closely related isomer[.]' by-products." *Id.* at 871. The Federal Circuit agreed noting "[i]t is clear from the record here that, although ISB was known in the prior art, the path to arrive at ISB with a purity of greater than 99.0% was not known before the relevant date of the '050 patent." *Id.* at 864.

The court reaffirmed that purified product patents may be patentable "if the process to arrive at the purified compound is itself of patentable weight" or "a mixture containing a compound . . . does not enable its purification." *Id.* at 871. The court also pointed to secondary factors supporting non-obviousness. Specifically, the failure of Allied, Sigma, Innovassynth and others in the art to reliably produce a high-purity ISB for 30 years. The supply disruption resulting in Coviden informing its customers that it was "completely out of" Lymphazurin® until it could find another supplier further supported non-obviousness. *Id.* at 871.

Bayer Pharma AG v. Watson Laboratories, 874 F.3d 1316 (Fed. Cir. 2017)

In *Bayer Pharma AG v. Watson Labs.*, 874 F.3d 1316 (Fed. Cir. 2017) the Federal Circuit sent a message to district judges regarding the limited value of expert testimony that overemphasizes commercial activity and conflicts with prior art reference documents. The court reversed the district court's determination of non-obviousness for Bayer's patent on vardenafil orally disintegrating tablet ("ODT"), marketed as erectile dysfunction ("ED") drug Staxyn®. Without disturbing the district court's credibility assessment favoring the patent owner's expert, the Federal Circuit found legal error in the district court's approach to obviousness. Specifically, it faulted the district court for focusing primarily on testimony of patent owner's

33 The court reversed the district court's finding of likelihood of success on infringement of Mylan's process patents under the DOE (discussed *infra*), but upheld the injunction on the grounds of the purified ISB claims discussed here.

expert and failing to consider prior art references teaching various ODT forms of ED drugs. After weighing all evidence, including commercial success and copying, the Federal Circuit concluded that the claims were obvious.

Bayer's patent claims an ODT formulation of vardenafil hydrochloride trihydrate including sorbitol and mannitol:

8. A drug formulation in the form of an uncoated tablet which disintegrates rapidly in the mouth and releases the drug in the mouth without swallowing the tablet comprising vardenafil hydrochloride trihydrate, and at least two sugar alcohols.
9. The drug formulation according to claim 8, wherein said sugar alcohols are a mixture of sorbitol and mannitol.
11. The drug formulation of claim 8, wherein at least one sugar alcohol is sorbitol.

Id. at 1320. The district court found that the claims were non-obvious because (A) there was no motivation to make an ODT vardenafil formulation since there were no ODT ED drugs on the market, (B) there would have been no motivation to use both sorbitol and mannitol since ED drugs only used mannitol, and (C) the prior art taught away from formulating vardenafil as an immediate release composition based on concerns regarding bitterness of vardenafil. Finally, the district court credited Bayer's evidence of secondary factors of non-obviousness as further support for upholding the patent.

The Federal Circuit rejected the district court's reasoning with respect to obviousness. The court noted the district court's determination regarding a lack of motivation to make an ODT vardenafil formulation was largely based on expert testimony about the lack of ODT ED formulations on the market. But Watson relied on nine references to support its argument that there would have been a motivation to create an ODT formulation of vardenafil—six of which “identify ED drugs as ODT formulations” yet were disregarded by the district court. *Id.* at 1322. Further, Watson's expert testified about several ODT ED drugs that were under development. According to the Court, “the motivation to formulate an ODT version of vardenafil is plainly evident from the face of multiple prior art references disclosing ODT formulations of ED drugs [and] [n]o further rationale for developing vardenafil ODT was necessary.” *Id.* at 1324.

While FDA approval may be relevant to the obviousness inquiry, . . . a lack of FDA approval cannot negate an otherwise apparent motivation to formulate a product.

The Federal Circuit also disagreed with the district court's finding that there would have been no motivation to use both sorbitol and mannitol. The parties agreed it was “known—if not necessary—to include a sugar alcohol in ODT formulations.” *Id.* The dispute centered on whether one would select a combination of sugar alcohols sorbitol and mannitol. The district court found Bayer's expert more credible than Watson's expert. The Federal Circuit stated, without calling into question the district court's credibility determinations, that “the district court's analysis for the sorbitol and mannitol limitation again focused on the commercial availability of products while failing to address relevant prior art.” *Id.* at 1325.

The court pointed to the commercially available ODT excipient Pharmaburst B2 which contained mannitol and sorbitol. Moreover, the court dismissed expert testimony that a person of ordinary skill in the art would look to what had been approved by the FDA to determine what would be a suitable excipient. The court noted that motivation need not be limited to what the FDA would approve:

There is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval. Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications.

Id. at 1326.

The Federal Circuit also found that the district court's concerns regarding Vardenfil did not amount to a teaching away:

We do not disturb the district court's findings relating to Vardenafil's expected bitter taste and increased bioavailability, but the district court erred when it elevated those findings to teaching away.

Id. at 1327. The Federal Circuit noted that ODT tablets were available in immediate and delayed release, and “[w]hen there are only two possible formulations and both are known in the art at the time, the fact that there may be reasons a skilled artisan would prefer one over the other does not amount to a teaching away from the lesser preferred but still workable option.” *Id.* at 1327.

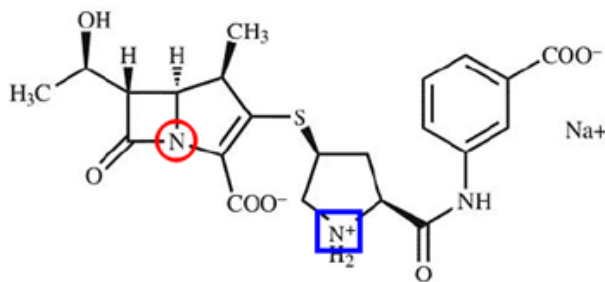
The court summarized Bayer's objective evidence of secondary considerations in a single paragraph, concluding

the “evidence of copying and unexpected results weigh in favor of the nonobviousness of the claimed combination.” *Id.* at 1328. The court, however, found “repeated suggestion in the prior art to make an ODT formulation of an ED drug and the suggestion to use the combination of sorbitol and mannitol as excipients are strong evidence of a motivation to make the claimed combination.” *Id.* at 1329. The court concluded that “[w]eighing this evidence together with the objective evidence of unexpected results and copying, we conclude that a skilled artisan would have found the claimed combination obvious.” *Id.*

Merck Sharp & Dohme v. Hospira, 874 F.3d 724 (Fed. Cir. 2017)

In *Merck Sharp & Dohme v. Hospira*, 874 F.3d 724 (Fed. Cir. 2017) the Federal Circuit affirmed a district court ruling that Merck’s patents covering its method of making Invanz® were obvious. Invanz® is a carbon dioxide adduct of ertapenem, a previously known but unstable antibiotic agent. The court found that the three claimed steps for making the carbon dioxide adduct would have been obvious in view of several prior art references. The strength of the obviousness case, moreover, outweighed secondary factors of non-obviousness, including commercial success and copying. The dissent by Judge Newman highlights a divergence of opinion as to the appropriateness of weighing the strength of a prima facie case (the first three *Graham* factors) against secondary considerations (the fourth *Graham* factor), rather than weighing all four *Graham* factors together.

Merck’s patent is directed to make a stable formulation of ertapenem, the antibiotic compound:



Ertapenem is known to be unstable because of two degradation reactions—hydrolysis of the lactam nitrogen (highlighted by a red circle) and dimerization via the pyrrolidine nitrogen (highlighted by a blue square). The prior art taught that ertapenem can be stabilized from dimerization by reacting the pyrrolidine nitrogen with carbon dioxide to form a “carbon dioxide adduct.”

Merck’s process claims involved preparing a “final

formulation” of a compound (including ertapenem) by conducting the following three steps:

1. Charging a solution of carbon dioxide source having a pH range of about 6.0 to about 12.0 into a reaction vessel;
2. Adding an effective amount of a mole ratio of a base and an active ingredient into the reaction vessel containing the solution of carbon dioxide source to maintain pH at about 6.0 to about 9.0 and a temperature range of about -3°C . to about 15°C .; and
3. Lyophilizing the solution of Step (2) to yield the final formulation product of a compound of formula Ia with less than about 10% of moisture content.

Id. at 726–27. The district court found that “while none of the three steps . . . was individually taught by the prior art, the ‘recipe’ for the final formulation was disclosed and the three steps leading to that formulation were nothing more than conventional manufacturing steps that would have been obvious from the disclosures and thus were the product of routine experimentation.” *Id.* at 727. The district court concluded that Merck showed commercial success and copying, “but that the objective evidence could not overcome the ‘strong prima facie case of obviousness.’” *Id.* at 728.

[I]t was reasonable for the district court to deduce from the evidence that the order and detail of the steps, if not already known, would have been discovered by routine experimentation while implementing known principles.

The Federal Circuit affirmed the prima facie case of obviousness, finding “[t]he only elements of [the claimed] process that were not expressly disclosed in the prior art are . . . the order of the steps, the simultaneous addition of base, the specific temperature range, and a final moisture content of less than 10%.” *Id.* at 730. While Merck argued that “the specific order and detail of the claimed steps constitute a novel solution to minimizing degradation by *hydrolysis*—a problem not addressed by the prior art—while operating in the pH range of 6.0–9.0, as disclosed in the prior art for minimizing *dimerization*.” *Id.* at 729 (emphasis original). The Court, however, noted “Merck’s problem is that the purported ‘solution’ for minimizing both degradation pathways constitutes nothing more than conventional manufacturing steps that implement principles disclosed in the prior art.” *Id.*

The Federal Circuit affirmed the district court’s conclusion that Merck’s objective evidence did not overcome the prima facie case of obviousness. The court clarified that “Merck’s



evidence of commercial success should not have been discounted simply because of the existence of another patent of which Merck was the exclusive licensee.” *Id.* at 730. The court also rejected Hospira’s argument that “evidence of copying is not compelling in the context of ANDA cases,” explaining that the Hatch-Waxman Act does not “require the generic manufacturer to copy the NDA holder’s process of manufacturing the drug.” *Id.* at 731. The court, however, found no “clear error in the district court’s determination that Merck’s evidence of commercial success could not overcome the weight of the evidence that the claimed process was substantially described in the prior art.” *Id.* at 731.

Judge Newman’s dissent highlighted disagreement over handling the *Graham* factors for determining obviousness. There are four *Graham* factors: (1) scope and content of prior art; (2) differences between claimed invention and prior art; (3) level of ordinary skill in field of invention; and (4) objective considerations (e.g., commercial success). Judge Newman suggested the majority “have sought a shortcut, and converted three of the four *Graham* factors into a self-standing ‘prima facie’ case, whereby the objective considerations must achieve rebuttal weight.” *Id.* at 732. According to Judge Newman, the Supreme Court has established that “it is incorrect to consign the objective evidence to rebuttal against the other three *Graham* factors.” *Id.*

Judge Newman is correct that there is a split in the Federal Circuit’s treatment of the *Graham* factors. Indeed, this was borne out in *Bayer* (weighing all factors) and *Merck* (establishing prima facie case and using objective evidence for rebuttal). In both cases, the Federal Circuit found obviousness in view of the prior art—notwithstanding the objective evidence (e.g., copying). Therefore, while uniformity in the court’s treatment of the *Graham* factors should be maintained, these cases suggest that the end result will be the same regardless of which approach the court takes.

Another takeaway from *Bayer* and *Merck* is the court’s acceptance of copying evidence in ANDA cases. In prior years, the court has held that copying is not relevant in ANDA cases. *See, e.g., Bayer Healthcare v. Watson Pharms., Inc.*, 713 F.3d 1369, 1377 (Fed. Cir. 2013) (“[E]vidence of copying in the ANDA context is not probative of nonobviousness because a showing of bioequivalence is required for FDA approval.”). We expect that this issue will continue to be litigated in future cases.

Written Description

Amgen v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017)

In *Amgen v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017) the Federal Circuit overturned an injunction upholding Amgen’s patents and enjoining Sanofi from selling Praluent® (alirocumab), an antibody for reducing low-density lipoprotein cholesterol (LDL-C) or “bad cholesterol.” In reaching its decision, the court resolved several important written description issues. First, the court held district court erred in excluding Amgen’s evidence of post-filing-date examples since such examples were relevant to whether the specification discloses representative species to support the genus. Second, the Federal Circuit rejected the “newly characterized antigen” test which, according to the court, “flouts the basic legal principles of the written description requirement.” *Id.* at 1378. Third, the Federal Circuit upheld the district court’s decision that Sanofi did not establish a PCT publication was prior art as of its provisional filing date because the provisional disclosure Amgen did not show that the provisions provided written description support for the claims in the PCT application.

The claimed antibodies are PCSK9 inhibitors, which block PCSK9 from destroying receptors (LDL-R) that bind to and destroy LDL-C. Amgen began studying PCSK9 in 2005, resulting in development of its product Repatha²²¹² which uses active ingredient evolocumab, a monoclonal antibody that targets PCSK9. Amgen’s patent claims “cover the entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to LDL-Rs” as follows:

An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDL[-]R

Id. at 1372. The patent specification discloses Amgen’s trial-and-error process starting with screening 3,000 monoclonal antibodies for PCSK9 activity. The list was eventually narrowed to 85 antibodies showing activity. The specification contained crystallography details for two antibodies and listed twenty-two which were known to compete for binding on PCSK9.

Simply, post-priority-date evidence of a particular species can reasonably bear on whether a patent

“fails to disclose a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus.”

The Federal Circuit first reviewed the district court’s decision to exclude post-priority-date evidence about antibodies, including the accused product Praluent. The District Court excluded this evidence because it “did not ‘illuminate[] the state of the art *at the time of filing.*” *Id.* at 1373. The Federal Circuit acknowledged that “written description is judged based on the state of the art as of the priority date,” and therefore post-priority-date evidence is not relevant to illuminate the state of the art. *Id.* However, “Appellants offered Praluent and other post-priority-date antibodies to argue that *the claimed genus fails to disclose a representative number of species.*” *Id.* at 1373 (emphasis added). The court noted that in its earlier decision *Abbvie Deutschland GmbH v. Janssen Biotech*,³⁴ both the Federal Circuit and district court relied heavily on the accused product to show the claimed genus lacked a disclosure of representative species. *Id.* at 1374. Accordingly, the Federal Circuit reversed the district court and remanded for a new trial. Interestingly, the use of post-filing evidence related to written description appears to be on the rise.³⁵

[T]he “newly characterized antigen” test flouts basic legal principles of the written description requirement. Section 112 requires a “written description of the invention.” But this test allows patentees to claim antibodies by describing something that is not the invention, i.e., the antigen.

The Federal Circuit then turned the district court’s instruction to the jury on written description. At issue was the “newly characterized antigen” test incorporated into the following jury instruction:

In the case of a claim to *antibodies*, the correlation between structure and function may also be satisfied by the disclosure of a *newly characterized antigen* by its structure, formula, chemical name, or physical properties if you find that the level of skill and knowledge in the art of

antibodies at the time of filing was such that *production of antibodies against such an antigen was conventional or routine.* (emphasis added)

Id. at 1376 (emphasis added). The court noted the “newly characterized antigen” test “traces its roots back to PTO guidelines first discussed by this court in *Enzo Biochem.*” *Id.* at 1376. The court noted that this holding was not central to its earlier decisions *Noelle* and *Enzo*, and “*Centocor* is the only case where we examined [it] in some detail.” *Id.* at 1377. In *Centocor*, the court “questioned the propriety of the ‘newly characterized antigen’ test and concluded that instead of ‘analogizing the antibody-antigen relationship to a key in a lock, it was more apt to analogize it to a lock and a ring with a million keys on it.” *Id.*

The court noted “[a] jury would naturally understand the instruction to permit it to deem any antibody within the claim adequately described merely because the antibody could easily be ‘produc[ed]” *Id.* But the Federal Circuit’s *en banc Ariad* decision held: “to satisfy the statutory requirement of a description of the invention, it is not enough for the specification to show how to make and use the invention, i.e., to enable it.” *Id.* By allowing the jury to conclude there was “adequate written description merely from a finding of ability to make and use, “the jury instruction “ran afoul of what is perhaps the core ruling of *Ariad.*” *Id.* at 1378. Accordingly, the court reversed the district court ruling and remanded for a new trial on written description.

[F]or a non-provisional application to claim priority to a provisional application for prior art purposes, “the specification of the provisional [application] must contain a written description of the invention . . . to practice the invention claimed in the non-provisional application.”

Sanofi sought to attack the district court’s judgment that Amgen’s patent claims were non-obvious on the grounds that the court improperly excluded the references, two published PCT applications. The published PCT applications themselves had an international filing date after the critical date of Amgen’s patent, but each claimed priority to a provisional application that predated the Amgen’s patent. Sanofi, however, did not proffer any evidence that

34 *Abbvie Deutschland GmbH v. Janssen Biotech*, 759 F.3d 1285 (Fed. Cir. 2014).

35 *See Stanford v. Chinese University*, 860 F.3d 1367 (Fed. Cir. 2017) (“The Board’s inquiry may include an analysis of whether the record contains testimony or evidence, relevant to this written description analysis, showing that any post-filing date publications contain art-related facts on random MPS sequencing or Illumina products existing on the filing date.”).

the claimed invention of those PCT applications was adequately supported by the provisional applications.

The Federal Circuit noted that “[i]n *Dynamic Drinkware*, we clearly explained that for a non-provisional application to claim priority to a provisional application for prior art purposes, ‘the specification of the provisional [application] must contain a written description of the invention . . . in such full, clear, concise, and exact terms, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.’” *Id.* at 1380. The court disagreed with Sanofi’s argument that *Dynamic Drinkware* applied only to patents, not published applications. The court faulted Sanofi for not “proffer[ing] any evidence showing that the provisional applications contained representative species or common structural elements sufficient to satisfy the written description requirement for the monoclonal antibodies claimed in the PCT applications.” *Id.*

The *Dynamic Drinkware* standard for establishing prior art effect of a provisional application is particularly cumbersome for defendants in those arts, such as antibodies, where written description attacks are common. The proponent of the prior art must argue that claims of a prior art reference meet the written description requirement even though published application claims were never granted, or even examined in some cases. *Amgen v. Sanofi* and *Dynamic Drinkware* pertain to pre-AIA cases where controlling § 119(e) stated that the provisional filing date could only be obtained for inventions “disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application.” Going forward, however, AIA cases will be governed by 35 U.S.C. § 102(d), which unlike the predecessor statute states that a provisional application “shall be considered to have been effectively filed, with respect to *any subject matter described in the patent or application . . . if the patent or application for patent is entitled to claim a right of priority under section 119.*” (emphasis added).

This court’s decision will inevitably lead to future challenges of biotech patent claims, especially against patents issued years ago. The court endorsed the use of post-filing date evidence to demonstrate a failure to disclose a representative number of species. A “representative number of species” is determined on a case-by-case basis, and thus it is difficult to ascertain whether a disclosure meets this criteria at the time of filing or even during prosecution. For example, a patent examiner is unlikely to be aware of post-filing date species that could impact the written description analysis under *Amgen*. As such, even if an applicant obtains a genus claim, it is unclear that the claim will be upheld by a court. Accordingly, a patent applicant should (1) disclose different types of species within the genus; (2) disclose structural

features common to members of the genus; and (3) include claims of varying scope to maximize its chances against a challenge. Of course, this is much easier said than done!

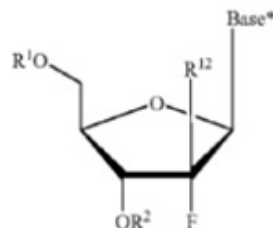
Enablement

Storer v. Clark, 860 F.3d 1340 (Fed. Cir. 2017)

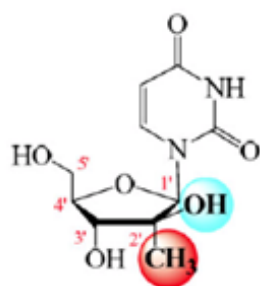
In *Storer v. Clark*, 860 F.3d 1340 (Fed. Cir. 2017) the Federal Circuit grappled with whether a provisional application disclosure of chemical synthesis pathways for related compounds, taken in combination with publicly available information, provides an enabling disclosure for claiming a target compound for treating hepatitis. The case arose out of an interference proceeding in which the Board denied Storer the benefit of a constructive reduction to practice of its earlier provisional application due lack of enablement for making the target compound. On that ground, the Board awarded priority to Clark, and the Federal Circuit affirmed. This case highlights the difficulty of relying on information outside one’s own disclosure to show the claims are enabled.

[T]he synthetic schemes in Storer’s provisional application do not teach or suggest conversion of any precursor into the 2’F(down) structure, and ... the Matsuda synthesis of a corresponding 2’-methyl (down), 2’-hydroxyl (up) structure does not enable a person of ordinary skill to produce the target compounds without undue experimentation

The Federal Circuit noted that “[t]he Storer provisional specification does not describe synthesis of the 2’F(down) target compounds” having the following structure:

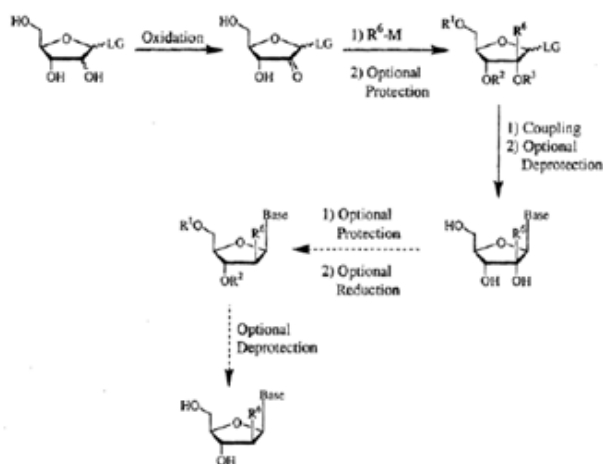


Id. at 1350. Storer argued, however, that several synthetic pathways disclosed in its provisional application (e.g., Scheme 3 below) taken with Compound 17 of Matsuda—a prior art reference—provide sufficient information to enable the invention.



Matsuda Compound 17

Scheme 3



The court reviewed three synthetic pathways described in Storer's provisional (e.g., Scheme 3 above) and found none of them disclose a 2'F(down) structure.

The Federal Circuit highlighted the level of undue experimentation (Wands Factor #1) and predictability or unpredictability in the art (Wands Factor #7). The court pointed to evidence of Storer's continuing research after the provisional was filed, and noted that the Board considered the fact that Clark was able to synthesize the compound in "a few months." *Id.* at 1352. With respect to predictability, the court credited the Board's finding that "fluoridation of tertiary alcohols, was highly unpredictable, as evidenced by Idenix's repeatedly unsuccessful attempts to synthesize its high-priority target nucleoside." *Id.* at 1351. Further, expert testimony supported the Board's findings: "A lot of things which look simple on paper in related systems have been tried and don't work in this series. Having to make the tertiary fluoride is very different to [sic] having to make secondary." *Id.* Accordingly, the Federal Circuit affirmed the Board's decision awarding priority to Clark.

Indefiniteness

BASF Corp. v. Johnson Matthey Inc.,
875 F.3d 1360 (Fed. Cir. 2017)

In *BASF v. Johnson Matthey*, 875 F.3d 1360 (Fed. Cir. 2017) the Federal Circuit reversed a district court's judgment that claims to a catalytic converter were indefinite. The district court found the language "composition ... effective to catalyze" made it impossible for a person of ordinary skill in the art to "determine which materials are within the 'material composition A' or 'material composition B' limitations, and which are not," according to the district court. The Federal Circuit, however, found no such evidence to support indefiniteness and several examples of known catalysts in the art. The Federal Circuit's decision, which discusses several recent indefiniteness cases provides useful guidance showing how evidence can be used to support an indefiniteness challenge that meets the standard articulated by the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*³⁶

[W]e have long held that nothing in the law precludes, for indefiniteness, "defining a particular claim term by its function."

Initially, the court clarified that "the *Nautilus* standard of 'reasonable certainty' does not exclude claim language that identifies a product by what it does." *Id.* at 1366. The indefiniteness analysis, instead, requires "a context-specific inquiry into whether particular functional language actually provides the required reasonable certainty." *Id.* at 1366. The context of the claims showed the "claimed arrangement" rather than "selection of particular catalysts" that distinguishes over the prior art:

A catalyst system for treating an exhaust gas stream containing NO_x, the system comprising:

at least one monolithic catalyst substrate having an inlet end and an outlet end; an undercoat washcoat layer . . . containing a material composition A *effective for catalyzing* NH₃ oxidation;

an overcoat washcoat layer . . . containing a material composition B *effective to catalyze* selective catalytic reduction (SCR) of NO_x; and

36 *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120 (2014).

wherein material composition A and material composition B are maintained as physically separate catalytic compositions.

Id. at 1362–63. The Federal Circuit noted the district court did not consider this claimed context, and that the claimed arrangement of the particular catalysts “rather than the selection of the particular catalysts, that purportedly renders the inventions claimed in the ‘185 patent a patentable advance over the prior art.” *Id.* at 1367.

The court explained how prior Federal Circuit cases holding claims indefinite relied on evidence supporting the Court’s indefiniteness holding:

- The claim term “slope of strain hardening coefficient” was indefinite where there were three methods of measuring it including the “10% secant tangent method,” “final slope method,” and “most linear method” all of which produced different results. *Dow Chemical Co. v. Nova Chemicals Corp.*, 803 F.3d 620, 633–35 (Fed. Cir. 2015).
- The claim term “molecular weight” could mean any one of Mp, Mn, or Mw and during prosecution “the patentee in one instance stated that it was Mw and in the other stated it was Mp.” *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1342–45 (Fed. Cir. 2015).
- The claim term “fragile gel” was the point of novelty but the specification does not distinguish how the “fragile gels” claimed in the ‘832 patent performed differently than the disclosed prior art. *Halliburton Energy Services, Inc. v. M-1 LLC*, 514 F.3d 1244, 1252–54 (Fed. Cir. 2008).
- The claim term “melting point elevation” could be measured using four different sample preparation methods where the “choice of sample preparation method is critical to discerning whether a particular product is made by a process that infringes the ‘976 patent claims.” *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332, 1340–42 (Fed. Cir. 2003).

[W]hether by reference to the specification or other intrinsic evidence or by reference to extrinsic evidence. . . . support was central to our determination that indefiniteness of certain physical-property claims was proved.”

The Federal Circuit noted that there was a lack of evidence supporting the district court’s finding that a person “could

not determine which materials are within the ‘material composition A’ or ‘material composition B’ limitation, and which are not.” *Id.* at 1366. Such supporting evidence “was central to our determination that indefiniteness of certain physical-property claims was proved.” *Id.* The court noted that “materials capable of performing the claimed reactions were known in the art at the time of the invention.” *Id.* at 1368. In addition, objective tests for determining the effectiveness of catalysts were known at the time of the invention. The court thus concluded the “record . . . does not contain intrinsic or extrinsic evidence that would support a judgment of indefiniteness.” *Id.* at 1368.

Presidio Components v. American Technical Ceramics, 875 F.3d 1369 (Fed. Cir. 2017)

The Federal Circuit in *Presidio Components v. American Technical Ceramics*, 875 F.3d 1369 (Fed. Cir. 2017) affirmed a district court’s decision upholding claims requiring a “fringe-effect capacitance . . . that is capable of being measured” against a challenge for indefiniteness. The patent owner successfully argued that even though the precise method of measuring fringe capacitance was not described in the patent, a person having ordinary skill in the art could have figured out how to measure it using techniques described in the patent. Unlike other cases finding claims indefinite for failure to specify a test method, the claims here did not require comparing measured values for an accused product with express numerical limits in the claim. Therefore, the choice of measurement had no effect on the claim’s scope.

Under our post-Nautilus cases, a claim is not indefinite if a person having ordinary skill in the art would know how to utilize a standard measurement method, such as insertion loss, to make the necessary measurement.

The specification taught a method of measuring capacitance called “insertion loss testing.” However, it lacked any teaching of how to apply the insertion loss method to determine the portion of the overall capacitance that is attributable to fringe effect capacitance as required by the claim. During trial, however, the patent owner’s expert testified that a person having ordinary skill in the art would know how to measure the fringe effect capacitance indirectly by measuring the capacitance using insertion loss testing both before and after removing the dielectric material of the capacitor.

The court upheld the district court’s definiteness holding on the grounds that a person having ordinary skill in the art could make the measurement called for by the claims. The court emphasized that as long as a skilled person would choose an established method the claim would

be definite “even if that method is not set forth *in haec verba* in the patent itself.” *Id.* at 1376. Further, the court distinguished cases holding claims indefinite where the challenger “has shown that there were competing existing methodologies that reached different results, and the patent failed to describe which of the multiple methods to use.” *Id.* at 1377. This case shows that courts will be reluctant to find indefiniteness where the scope of the claim can be understood. A slightly different picture is emerging in the Patent Office, which has just asserted that the standard making an indefiniteness rejection within the Patent Office is easier to satisfy than in the courts.³⁷

Claim Construction/ Infringement

Shire Development v. Watson Pharmaceuticals, 848 F.3d 981 (Fed. Cir. 2017)

In *Shire Development v. Watson Pharmaceuticals*, 848 F.3d 981 (Fed. Cir. 2017) the Federal Circuit reversed a district court judgment that Watson’s ANDA infringed Shire’s patent for its \$800 million mesalamine drug, LIALDA®. The court found that close-ended terminology “consists of” used within certain elements of the body of the claim worked to exclude from the scope of the claim Watson’s proposed generic composition due to the presence of magnesium stearate in the drug’s outer hydrophilic matrix. The Federal Circuit’s decision highlights the “very strong presumption that a claim element is ‘closed’” when the claim body includes close-ended language, such as “consists of.” This case provides yet another example where close-ended terminology used in the body of a claim inadvertently overrides an open-ended transitional phrase “comprising” in the claim’s preamble.

Shire’s patent claims a controlled release oral pharmaceutical composition using a combination of open- and close-ended transitional language throughout the claim:

1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, *comprising*: (a) an inner lipophilic matrix consisting of substances selected from the group consisting of unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid

mono-, di- or triglycerids, waxes, ceramides, and cholesterol derivatives with melting points below 90°C., and wherein the active ingredient is dispersed both in said [sic] the lipophilic matrix and in the hydrophilic matrix; (b) an *outer hydrophilic* matrix wherein the lipophilic matrix is dispersed, and said *outer hydrophilic matrix consists of* compounds selected from the group consisting of polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrans, pectins, starches and derivatives, alginic acid, and natural or synthetic gums; (c) optionally other excipients....

Id. at 983. Watson’s proposed generic composition included an extragranular space, corresponding to the outer hydrophilic matrix, which includes “magnesium stearate”—a component not listed in claim element 1(b):

Extragranular Excipient Composition

Excipient	Amount (mg)	Property
Sodium Starch Glycolate (SSG)	<34 (unknown)	Hydrophilic
Magnesium Stearate	<7 (unknown)	Lipophilic
Colloidal silicon dioxide	4	

Id. at 985. The district court found that Watson’s proposed generic infringed, however, “because the component outside of the Markush group—i.e., the lipophilic magnesium stearate in the hydrophilic outer matrix—is unrelated to the invention.” *Id.* The district court credited expert testimony that the SSG is more potent than the magnesium stearate, and found that “magnesium stearate in the extragranular space is *overwhelmed* by the hydrophilic properties of the sodium starch glycolate in the extragranular space.” *Id.* (emphasis added) Shire further argued in support of the judgment that the magnesium stearate is a lubricant and is not relied on for its hydrophilic properties.

Norian did not restrict “related” components to only those that advance or are intended to

37 *Ex parte Gerard*, Appeal No. 2015-006416, Application No. 13/435,655 (PTAB Aug. 25, 2017) (“The Office’s application of the broadest reasonable interpretation for pending claims and its employment of an interactive process for resolving ambiguities during prosecution naturally results in an approach to resolving questions of compliance with § 112 that fundamentally differs from a court’s approach to indefiniteness. To that end, the Office’s approach effectively results in a lower threshold for ambiguity than a court’s.”).

advance a Markush group’s allegedly inventive elements, which would in effect equate the scope of a Markush group’s “consisting of” language with either “comprising” or “consisting essentially of.”

The Federal Circuit noted that the term “consisting of” “creates a very strong presumption that that claim element is ‘closed’ and therefore ‘exclude[s] any elements, steps, or ingredients not specified in the claim.” *Id.* at 984. The Court, however, acknowledged that “[t]hrough the ‘consisting of’ presumption is very strong, we permit the rare exception for ‘aspects unrelated to the invention’” under *Norian v. Stryker*.³⁸ In *Norian*, the claim was to a kit for dental applications “consisting of” two chemical components. The accused product, however, included in addition to the chemical components a spatula for mixing the chemical components. The Federal Circuit held in *Norian* that “[i]nfringement is not avoided by the presence of the spatula, for the spatula has no interaction with the chemicals, and is irrelevant to the invention.” *Id.* at 985.

The court rejected Shire’s argument that the magnesium stearate was unrelated to the invention because it did not “advance the Markush group’s allegedly inventive elements.” *Id.* at 986. Specifically, Shire argued that it was insufficiently lipophilic and was being used for its lubricant properties. But the court found that such approach “would in effect equate the scope of a Markush group’s “consisting of” language with either “comprising” or “consisting essentially of” language. *Id.* Shire also argued that the examples of the patent include magnesium stearate in the outer matrix. But that too did not sway the Court, which held that “consisting of” should have its “well established, limited definition.” *Id.* In holding non-infringement, the court demonstrated that presumption that “consisting of” excludes additional components trumps other claim construction principles such as “a claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct.”³⁹

Proving Infringement

Eli Lilly & Co. v. Teva Parenteral Medicines,
845 F.3d 1357 (Fed. Cir. 2017)

In *Eli Lilly & Co. v. Teva Parenteral Medicines*, 845 F.3d 1357 (Fed. Cir. 2017) the Federal Circuit affirmed a district

court judgment that Teva’s proposed generic of Eli Lilly’s Alimta® product would infringe patent claims covering co-administration of pemetrexed, a methylmalonic acid-lowering agent (vitamin B12), and folic acid. The drug label instructed the patient to self-administer folic acid, while instructing the prescribing physician administer pemetrexed and vitamin B12, but only if the patient has taken folic acid as instructed. The infringement issue centered on whether the patent’s action in taking folic acid could be attributed to the physician such that one single entity—the physician—can be charged with performing every step of the claimed method as required to show induced infringement under *Akamai Techs. v. Limelight Networks*. The Federal Circuit’s decision finding infringement shows that a patent holder can prove infringement using a drug label that instructs a patient to self-administer one component of a co-administration claim. However, the case made clear that more than a mere patient-physician relationship will be needed.

The patent claim at issue was to a method of therapeutic co-administration of three active ingredients:

1. A method of administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of **folic acid** and an effective amount of a **methylmalonic acid lowering agent** followed by administering an effective amount of **pemetrexed disodium**, wherein the methylmalonic acid lowering agent is selected from the group consisting of **vitamin B12**. . . . (emphasis added)

Id. at 1362. The drug product label included both Physician Prescribing Information and Patient Information sections. The Physician Prescribing Information section tells the physician to “instruct patients” to take folic acid before pemetrexed:

Instruct patients to initiate folic acid 400 [µg] to 1000 [µg] orally once daily beginning 7 days before the first dose of [pemetrexed]....” J.A. 11256.

Instruct patients on the need for folic acid and vitamin B12 supplementation to reduce treatment-related hematologic and gastrointestinal toxicity....” J.A. 11278.

³⁸ *Norian v. Stryker*, 363 F.3d 1321, 1331 (Fed. Cir. 2004).

³⁹ *On-Line Techs. v. Bodenseewerk Perkin-Elmer*, 386 F.3d 1133, 1138 (Fed.Cir. 2004).

Id. at 1364. The Patient Information also discussed the need to take folic acid along with pemetrexed:

To lower your chances of side effects of [pemetrexed], you must also take folic acid ... prior to and during your treatment with [pemetrexed].” J.A. 11253 (emphasis omitted).

It is very important to take folic acid and vitamin B12 during your treatment with [pemetrexed] to lower your chances of harmful side effects. You must start taking 400–1000 micrograms of folic acid every day for at least 5 days out of the 7 days before your first dose of [pemetrexed]....” *Id.* (emphasis omitted).

Id. The drug product label thus instructs the patient to take folic acid, and the physician to administer pemetrexed and vitamin B12 to the patient.

Under 35 U.S.C. 271(b), “whoever actively induces infringement of a patent shall be liable as an infringer.” Inducement requires that the alleged infringer “‘knew or should have known his actions would induce actual infringements.” *Id.* But in order to induce infringement, direct infringement by one party or multiple parties working together is required.

The court noted that under *Akamai*, where no single actor performs all of the required method steps, direct infringement only occurs if the acts of one are attributable to the other such that a single entity is responsible for the infringement. The performance of method steps are attributable to another entity when that entity “directs or controls” the other’s performance, or when the actors “form a joint enterprise.” *Id.* Under *Akamai*, direction and control is a two prong analysis requiring “circumstances in which an actor: (1) ‘conditions participation in an activity or receipt of a benefit’ upon others’ performance of one or more steps of a patented method, and (2) ‘establishes the manner or timing of that performance.’” *Id.* at 1365.

What is relevant is whether the physician sufficiently directs or controls the acts of the patients in such a manner as to condition participation in an activity or receipt of a benefit — in this case, treatment with pemetrexed in the manner that reduces toxicities — upon the performance of a step of the patented method and establishes the manner and timing of the performance

Here, Lilly argued that the physicians direct or control their patient’s administration of folic acid. With respect to the first

prong of direction and control, the court framed the issue as whether “physicians ‘condition’ pemetrexed treatment on the administration of folic acid.” *Id.* at 1366. The court found that the product label repeatedly warns of the dangers of taking pemetrexed without folic acid preconditioning. Further, the Patient Information advises that the physician may withhold pemetrexed treatment. Eli Lilly’s expert testified that is “the physician’s responsibility to initiate the supplementation” of folic acid. *Id.* The court concluded prong (1) was satisfied. In doing so, the court rejected Teva’s arguments that there is no evidence that physicians verify compliance with taking folic acid, threaten denial of pemetrexed treatment, or impose a legal requirement to take folic acid. The court noted that none of these additional steps are required to meet the first prong of direction and control under *Akamai*.

With respect to prong (2) whether the physician establishes the manner and timing of performance, i.e., folic acid pretreatment, the court found this element was likewise met. The court again turned to the label information showing a dosing schedule for folic acid pretreatment. Eli Lilly’s expert testified furthermore that “‘it’s the doctor’ who ‘decides how much [folic acid] the patient will take and when the patient takes it.’” *Id.* at 1367. The court made clear that it was not laying down a blanket rule on what actions meet the “direction or control” requirement, and that more is required than the mere existence of a physician-patient relationship.

When the alleged inducement relies on a drug label’s instructions, “[t]he question is not just whether [those] instructions describ[e] the infringing mode, ... but whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent.

Having established direct infringement by the physician, the court turned to whether the Eli Lilly had proved Teva had the “specific intent and action to induce infringement.” *Id.* at 1368. Here the court noted that the prescribing information’s instruction for folic acid pretreatment was “a critical step.” The court clarified the standard for showing induced infringement based on a drug product label instructions involves an inquiry into “whether the instructions teach an infringing use such that we are willing to infer from those instructions an affirmative intent to infringe the patent.” *Id.* The court thus dismissed Teva’s arguments that it speculation as to how physicians may act in the real world. The court also noted we do not look at the prevalence of infringing activity so long as the label would inevitably lead some physicians to infringe. According to the Court, “[d]epending on the clarity of the instructions, the decision to continue seeking FDA approval of those instructions may be sufficient evidence



of specific intent to induce infringement.” *Id.* at 1368.

This decision shows that proving infringement of a co-administration claim may be difficult where the product label is vague as to how the other drug compound is administered. There may be insufficient evidence to tie infringement to a single party under the “direction or control” prong. Moreover, even if direction or control is found, the label’s vagueness about how the product is to be co-administered could lead to a finding of lack of specific intent to infringe.

Sanofi v. Watson Laboratories,
875 F.3d 636 (Fed. Cir. 2017)

In *Sanofi v. Watson Labs.*, 875 F.3d 636 (Fed. Cir. 2017) the Federal Circuit affirmed a district court decision that Watson and Sandoz’s ANDAs induced infringement of Sanofi’s patent covering Multaq® (dronedarone). The patent was directed to decreasing a risk of cardiovascular hospitalization in a patient and claimed administering dronedarone to patients having several enumerated risk factors mirroring the patient population in Sanofi’s ATHENA clinical trial. The court found that because the drug label indicated administering dronedarone to patients referring specifically to a summary of the ATHENA clinical trial, it would have directed physicians to administer the drug to patients having the required risk factors thereby infringing Sanofi’s patent. The court rejected arguments that substantial non-infringing uses could provide a defense against induced infringement, as they do for contributory infringement.

The method of treatment patent requires selection of patient population mirroring the criteria of Sanofi’s ATHENA clinical trial:

A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising administering to said patient an effective amount of dronedarone or a pharmaceutically acceptable salt thereof, twice a day with a morning and an evening meal, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: (a) NYHA Class IV heart failure or (b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent nonpermanent atrial fibrillation or flutter; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of: (a) an age greater than or equal to 75; (b) hypertension; (c) diabetes; (d) a history of cerebral stroke or

of systemic embolism; (e) a left atrial diameter greater than or equal to 50 mm; and (f) a left ventricular ejection fraction less than 40%.

Id. at 642. The label for Multaq® included the following “indications and usage” section:

Multaq® is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF) [see Clinical Studies (14)].

Id. at 642–43. The Clinical Studies section primarily describes the ATHENA study, and also contains short description of the EURIDIS and ADONIS studies as well as some other studies that terminated due to negative results. The ATHENA study description includes the same risk factors (i)–(vi) written into the patent claims.

Section 271(b), on inducement, does not contain the “substantial noninfringing use” restriction of section 271(c), on contributory infringement.

Watson and Sandoz argued that because Multaq® has substantial non-infringing uses not forbidden by the proposed labels, the district court could not permissibly find intent to encourage an infringing use. The Federal Circuit rejected this argument, noting that non-infringing uses do not preclude induced infringement. The court noted the absence of the statutory “substantial noninfringing use” restriction of contributory infringement within the inducement statute. Further, “the core holding of *Grokster*, a copyright decision that drew expressly on patent and other inducement law, is precisely that a person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses (like the peer-to-peer software product at issue there, which was capable of infringing and non-infringing uses).” *Id.* at 646. Accordingly, the court held “[t]here is no basis for a different inducement rule for drug labels.” *Id.*

The court noted that “for a court to find induced infringement, ‘[i]t must be established that the defendant possessed specific intent to encourage another’s infringement.’” *Id.* at 644. The district court compared the label including reference to the ATHENA trial to the patent claims and found the “proposed labels encourage physicians to prescribe dronedarone to patients with at least one of the cardiovascular risk factors claimed” in the patent. *Id.* The court compared the content of the label to the patent claim and concluded, “the content of the label in this case permits the inference of specific intent to encourage the infringing

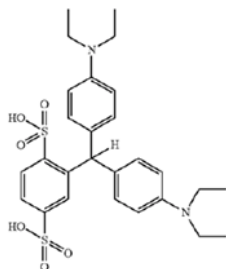
use.” *Id.* at 646. The court contrasted the case situations, such as *Takeda Pharms. USA v. Westward Pharm.*,⁴⁹ which involved speculation that doctors would use the drug to treat gout flare based on statement in the label that “[i]f you have a gout flare while taking Mitigare, tell your healthcare provider.”

Mylan Institutional v. Aurobindo Pharma, 857 F.3d 858 (Fed. Cir. 2017)

In *Mylan Institutional v. Aurobindo Pharma*, 857 F.3d 858 (Fed. Cir. 2017) the Federal Circuit weighed in on the thorny issue of doctrine of equivalents (DOE) in the chemical arts. On appeal from a district court’s grant of a preliminary injunction involving isosulfan blue (“ISB”), a dye used to map lymph nodes, the court reversed the a finding that Mylan could demonstrate likelihood of success on the merits that Aurobindo’s process infringed several process patents under the DOE. The Federal Circuit found the district court’s function-way-result (FWR) analysis was deficient, and suggested that the insubstantial differences test “might seemingly be more appropriate” in chemical cases. The court upheld the preliminary injunction on the basis of another patent where only validity was challenged (discussed above), and noted that several factual issues exist for trial on the merits with respect to the DOE claim on Mylan’s process patents.

Mylan’s process patents relevant to the DOE issue required forming ISB by combining isoleuco acid with silver oxide in a polar solvent, followed by treatment with sodium:

A process of preparing N-[4-[[4-(diethylamino)phenyl] (2,5-disulfophenyl) methylene]-2,5cyclohexadien-1-ylidene]-N-ethylethanaminium, sodium salt comprising combining a suspension of isoleuco acid of the formula



in a polar solvent with silver oxide, recovering isosulfan blue acid, and treating the isosulfan

blue acid with a sodium solution.

Id. at 861–62. Aurobindo’s ANDA sought approval for ISB produced with a similar process that used manganese dioxide with acid rather than silver oxide, followed by preparatory HPLC to achieve an ISB purity of 99.5%.

The district court found that “the difference in oxidation strength between silver oxide and manganese dioxide is ‘irrelevant’ under both” the FWR and “insubstantial differences” test for DOE “as applied to the ‘face of the claims,’ because the claims do not specify a requirement of oxidation strength.” *Id.* at 863. The court found manganese oxide to be a mild oxidant equivalent to silver oxide in the context of the process patent and credited Mylan’s expert that the two reagents produced ISB in similar yields.

[W]e conclude that the district court’s analysis of equivalence in this case was flawed, no doubt because of the sparse and confusing case law concerning equivalents, particularly the paucity of chemical equivalence case law, and the difficulty of applying the legal concepts to the facts.

The court noted initially that few prior cases involve preliminary injunctions predicated on a DOE infringement claim, and very few cases exist for evaluating DOE in the chemical arts. The court noted that the “Supreme Court was surely correct in stating that non-mechanical cases may not be well-suited to consideration under the FWR test . . . [and that] seems to be particularly true in the chemical arts.” *Id.* at 867. The court made clear it would review the case under the FWR test because “[t]he district court here applied the FWR test in evaluating the equivalence issue.” *Id.* The court noted difficulty applying FWR to chemical cases because “it is often not clear that the ‘function’ or ‘way’ is for each claim limitation.” *Id.* For example, while the result may be self-evident in a chemical case; the “function” and “way” of a particular limitation may remain vague and often overlap, or be synonymous.

Even if evaluating the “function” and “way” prongs is feasible, the FWR test may be less appropriate for evaluating equivalence in chemical compounds if it cannot capture substantial differences between a claimed and accused compound.

Turning to the FWR analysis the Federal Circuit found the district court did not address Aurobindo’s argument

40 *Takeda Pharms. USA v. Westward Pharm.*, 785 F.3d 625 (Fed. Cir. 2015).



that the “function” prong of the FWR was not met because the difference in oxidation strength between silver oxide and manganese oxide. The Federal Circuit thought this argument “in actuality related to the ‘way’ component of the FWR test.” *Id.* at 868. The court noted that the district court did not properly evaluate “the relative oxidation strengths of silver oxide and manganese dioxide, as well as the use of an acid in the accused process.” *Id.* The court noted that “there is room for sufficient doubt as to whether silver oxide and manganese dioxide oxidize isoleuico acid in the same way so as to satisfy the ‘way’ prong of the FWR test.” *Id.* The court noted “[w]hen the case goes back to the district court for a full trial on the merits, the court may wish to consider whether the substantiality of the differences test may be more applicable in this case.” *Id.* at 869.

The court went on to explain how DOE analysis under the “insubstantial differences” test works—and in doing so showed how it provides a much more limited scope of equivalents than the FWR test. The court showed how aspirin and ibuprofen may “seem to be substantial equivalents under the FWR test” yet “chemists would not usually consider to be structural equivalents under the insubstantial differences test.” *Id.* Thus, “a compound may appear to be equivalent under the FWR test, but not under the substantiality of the differences test.” *Id.* The court went on to note that “[m]anganese oxide and silver oxide are substantially different in many respects.” *Id.* The court instructed the district court to conduct an insubstantial differences analysis after trial on the issue, in addition to a FWR analysis “if it determines that it should still utilize that test.” *Id.*

Derivation

Cumberland Pharms. v. Mylan Institutional, 846 F.3d 1213 (Fed. Cir. 2017)

In *Cumberland Pharms. v. Mylan Institutional*, 846 F.3d 1213 (Fed. Cir. 2017) the Federal Circuit affirmed a district court decision upholding Cumberland’s patent for a chelating-agent-free formulation of Acetadote®, against a challenge based on derivation. Under 35 U.S.C. § 102(f), a “patent applicant is not entitled to a patent if ‘he did not himself invent the subject matter sought to be patented.’” The Federal Circuit first clarified that derivation requires that another conceived the claimed invention, and communicated that conception to the named inventor. The court noted that “derivation is not proved by showing conception and communication of an idea different from the claimed invention even where that idea would make the claimed idea obvious.” The court thus focused on

whether documents showed that FDA suggested the concept of removal of EDTA from Acetadote®—without adding another chelator—to Cumberland’s inventor. The court found no evidence of derivation and therefore affirmed.

The critical correspondence between the FDA and Cumberland occurred during the approval process for Cumberland’s Acetadote® product, a composition previously approved in other countries. The FDA sent Cumberland a letter asking for the “scientific and regulatory justification for the inclusion of Edetate as a component in the drug product.” *Id.* at 1216. After a follow up phone conversation the FDA requested “justification for the inclusion of Edetate.” In response, Cumberland stated that Edetate had been added to stabilize the formulation and that “[i]f no or lower concentrations of edetate are capable of ensuring product stability, lowering or removing edetate would raise question how the safety and efficacy of the product would be affected.” *Id.* The inventor testified that shortly after this exchange he had the idea of testing the stability of an acetylcysteine formulation without EDTA. Cumberland informed the FDA that it would continue to evaluate an EDTA-free version of Acetadote® after approval, which the FDA acknowledged in its approval letter for Acetadote®.

Cumberland then engaged Bioniche Pharma Group—Mylan’s predecessor company—to conduct stability testing for an EDTA-free version of Acetadote®. Cumberland designed the protocol, which was approved by the FDA without changes. After stability data came back positive, Cumberland filed its patent application. Cumberland gave the FDA the final results of the stability study in 2008 to secure approval for an EDTA-free version of Acetadote®, which the FDA approved in January 2011. Later that year, Mylan filed an ANDA for an EDTA-free version of Acetadote®, and Cumberland sued Mylan for patent infringement.

[D]erivation is not proved by showing conception and communication of an idea different from the claimed invention even where that idea would make the claimed idea obvious.

Mylan’s derivation challenge focused on the rule that “an applicant is not entitled to a patent if ‘he did not himself invent the subject matter sought to be patented.’” 35 U.S.C. 102(f). The court noted that the 102(f) defense required Mylan to prove prior conception of the claimed subject matter followed by communication of that to the inventor. The court noted however, that “the inventors named on the issued patent are presumed to be correct” and “a person seeking to add his name ‘must meet the heavy burden of proving its case by clear and convincing evidence.’” *Id.* at 1218. In other words, Mylan had to show, by clear and convincing

evidence, that the FDA conceived the idea of an EDTA-free version of Acetadote® (or a similar product that met all of the other patent claim elements) with no other chelating agents, and communicated that idea to Cumberland.

Upon review, the Federal Circuit took a deferential review of the district court's holding that Cumberland did not derive the invention from the FDA: "The court could properly view the FDA's December 10, 2002 letter, which simply requested justification for the inclusion of EDTA in the drug product, as not showing the prior conception needed here." *Id.* at 1219. The court noted that it was not enough for Mylan to show that "the request for data to support the inclusion of EDTA required Cumberland to undertake research that would have inevitably led it to the invention." *Id.* Derivation "is not proved by showing conception and communication of an idea different from the claimed invention even where that idea would make the claimed idea obvious." *Id.* Indeed, "a 'general goal or research plan' does not constitute the 'definite and permanent idea' required for conception." *Id.*

Reexamination – Absolute Intervening Rights

Presidio Components v. American Technical Ceramics, 875 F.3d 1369 (Fed. Cir. 2017)

The Federal Circuit in *Presidio Components v. American Technical Ceramics*, 875 F.3d 1369 (Fed. Cir. 2017) upheld a district court determination that Presidio's reexamination claims were not substantially identical to its original patent claims, and therefore intervening rights precluded recovery for infringement pre-dating its reexamination certificate. The Federal Circuit rejected Presidio's arguments relating to its intent in making the amendment during reexamination. Instead, the court compared the claim wording and found a substantial narrowing of the claim that was used to overcome prior art during reexamination. Given the broader claim interpretation standard in the Patent Office versus district court, this case highlights the vulnerability of patent claims to reexamination where prior art may force an amendment that would not otherwise be needed under a district court's narrower claim construction.

[A] patentee's intent in making the amendment is not determinative or controlling in determining claim scope . . . it is irrelevant why an amended claim is narrowed during reexamination

Presidio's claim amendment during reexamination introduced the following underlying language:

The second contact being located sufficiently close to the first contact in an edge to edge relationship in such proximity as to form a first fringe-effect capacitance with the first contact that is capable of being determined *by measurement* in terms of a standard unit.

The district court compared the amended claims in the reexamination certificate with the claims as construed by the district court in a prior lawsuit, and found that the amendments substantially changed the claim scope.

The Federal Circuit agreed that the amendment did make explicit the part of the district court's construction; namely, that the claims require a fringe effect capacitance "that is capable of being determined in terms of a standard unit." *Id.* at 1378. However, the amended reexamination claims also added "by measurement." During reexamination, the examiner rejected the original claims in light of a prior art reference that disclosed a capacitor arrangement where the fringe-effect capacitance could be measured using a theoretical calculation. When Presidio added the "by measurement" to the claims it argued that "the amended claim language excludes determination of fringe-effect capacitance that 'rel[y] entirely upon theoretical calculation.'" *Id.* at 1379. Accordingly, the claim was narrowed to overcome prior art during reexamination.

The "substantially identical" requirement for reexamination involves a comparison of the reexamined claims with the original claims of the issued patent. "[I]f an amendment during reexamination make a substantive change to an original claim, the patentee is only entitled to infringement damages for the changed claim for the period following issuance of the reexamination certificate." *Id.* at 1378. The Federal Circuit concluded "[b]ased on this substantive change in claim scope, the district court properly granted the affirmative defense of absolute intervening rights." *Id.* at 1380. Thus, the damages period began with publication of the reexamination certificate.

Inequitable Conduct

Regeneron Pharms. v. Merus,
846 F.3d 1343 (Fed. Cir. 2017)

In *Regeneron Pharms. v. Merus*, 846 F.3d 1343 (Fed. Cir. 2017) the Federal Circuit affirmed a district court determination of inequitable conduct based on an adverse inference of deceptive intent in withholding material prior art references from the Patent Office. The adverse inference of deceptive intent stemmed from litigation misconduct during the



discovery phase of litigation. The court distinguished prior case law holding that unenforceability is an inappropriate remedy for litigation misconduct because in those cases inequitable conduct was not raised as a defense. Judge Newman dissented, noting “the panel majority [does not] cite a single case—at any level of the federal system—in which litigation misconduct was part of a finding of inequitable conduct.” *Id.* at 1367. On December 26, 2017, the court denied Regeneron’s request for rehearing *en banc* over the dissent of Judges Newman and Reyna. This case shows that where inequitable conduct is at issue in a litigation, the judge may infer deceptive intent based on conduct of the litigators many years after a patent is granted.

At issue were several references cited by a third party during prosecution of a related application. Regeneron did not submit these references in the application that led to the involved patent but did submit them in other pending applications. The district court held a bench hearing on materiality and issued an exhaustive opinion detailing the materiality of the withheld references. Instead of holding its planned second bench trial on specific intent to deceive the PTO, “in its opinion following the first bench trial, the court exhaustively detailed Regeneron’s discovery misconduct throughout litigation and sanctioned Regeneron by drawing an adverse inference of specific intent to deceive the PTO.” *Id.* at 1347. The court referred to “Regeneron’s repeated violations of the district court’s discovery orders and improper secreting of relevant and nonprivileged documents.” *Id.* Based on the litigation misconduct and the materiality of the disclosed references, the court found that Regeneron’s patents were unenforceable for inequitable conduct. The Federal Circuit upheld the district court’s finding that the withheld references were material and agreed with the district court as to the impropriety of the litigation misconduct.

Regeneron challenged whether a district court could draw an adverse inference of intent for inequitable conduct during patent prosecution based on litigation misconduct. Regeneron argued that under Second Circuit law an adverse inference may only be drawn against a specific piece of evidence. The Federal Circuit, however, found that the case Regeneron relied upon “confirms the

broad discretion of district courts in sanctioning parties for violating discovery obligations, and never limits the power of the district court to only apply adverse inferences against specific pieces of evidence that are missing, destroyed, or untimely produced.” *Id.* at 1363.

The majority opinion noted “[t]he dissent relies heavily on *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001), for the proposition that litigation misconduct cannot support a finding of unenforceability of a patent for inequitable conduct.” *Id.* at 1364. The majority noted that the district court in *Aptix* declared the patent unenforceable as a “penalty” for litigation misconduct under the doctrine of unclean hands. The Federal Circuit reversed because the doctrine of unclean hands “targets specifically the misconduct, without reference to the property right that is the subject of the litigation.” *Id.* at 1364. Here, the majority found that “Regeneron is accused not only of post-prosecution misconduct but also of engaging in inequitable conduct during prosecution.” *Id.* at 1364. The majority further concluded that Regeneron’s litigation misconduct “obfuscated its prosecution conduct.” *Id.* Given that inequitable conduct was at issue in the litigation where the misconduct occurred, the Federal Circuit agreed the district court judge was within his authority to draw an adverse inference of intent to deceive during prosecution in the Patent Office.

This case is troubling to patentees since it shows litigation misconduct—occurring *years after* prosecution—can lead to an unenforceable patent. Moreover, while a patent prosecutor cannot control the conduct of a future litigation, there are several actions that can be taken at the patent office. The obvious takeaway is “when in doubt, submit the document,” especially if the document was raised by a third party in a related patent application. For example, even if the document is discovered after allowance, an applicant can file a Request for Continued Examination or use Quick Path IDS Program (if applicable).⁴¹ If a patent has issued, documents can be submitted in an *ex parte* reexamination⁴² or Supplement Examination.⁴³

41 See <https://www.uspto.gov/patent/initiatives/quick-path-information-disclosure-statement-qpids>.

42 35 U.S.C. §§ 302-306.

43 35 U.S.C. § 257.

Conclusion

What's on the horizon for 2018?

In 2018, we expect the Supreme Court to decide the constitutionality of IPRs in *Oil States*⁴⁴ and whether the Board's practice of partial institution is allowed by statute in *SAS Institute*.⁴⁵ Either case would have a monumental impact if the Supreme Court were to reverse the Federal Circuit given the prevalence of IPR and the Board's partial institution practice.

The Federal Circuit decided *WiFiOne v. Broadcom*⁴⁶ *en banc* on January 8, 2018, overturning its earlier decision barring patent owners from challenging the Board's application of the one-year time bar of 35 U.S.C. § 315(b). This statute precludes petitioner from filing an IPR more than one year after it or its "privy" is served with a complaint for patent infringement. This decision will lead to the Federal Circuit interpreting the term "privy" as well as the Board's application of the time bar to many differing factual scenarios.

We may see an increase in patent owner victories on motions to amend in light of *Aqua Products*, and those cases may present unique procedural issues for appeal. Petitioners can oppose motions to amend using any patentability grounds, such as written description or enablement. Given that the burden is on petitioners, we will likely see procedural fairness arguments being raised as well as efforts to expand briefing before the Board. The Patent Office may issue new rules actually putting the burden back on the patent owner, and the *Aqua Products* decision seems to allow for enacting such a new rule although for the time being the Board is placing the burden on petitioners.

Another hot topic for 2018 will be sovereign immunity for drug companies that have transferred ownership of their patents to Native American tribes. The Board held that such patent cannot be challenged in IPR due to sovereign immunity of the tribes. Many have questioned the legitimacy of these deals, and there is likely to be significant litigation if not legislative action in this area. Recently, the Board held sovereign immunity waived for patents that have been litigated in district court thereby decreasing the impact of this strategy.

The number of biosimilar applications under the BPCIA

is expected to increase and although the Supreme Court clarified some issues in *Amgen v. Sandoz*, many issues pertaining to the procedure remain unresolved. We can expect to see more cases interpreting the provisions of the BPCIA over the coming year.

As to substantive law, we should see more cases applying provisions of the AIA. For example, while *Helsinn* held the non-informing public sale in that case was prior art under AIA and pre-AIA, we may see cases dealing with completely secret sales or uses that will require the court to look at this issue again. We also expect to see more challenges under 35 U.S.C. § 101, such as whether a claim directed to a method of treatment is patent eligible under the Supreme Court's *Mayo* framework.

44 *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, Case No. 16-712 (S.Ct.) (Argued No. 27, 2017).

45 *SAS Institute Inc. v. Matal*, Case No. 16-969 (S.Ct.) (Argued No. 27, 2017).

46 *WiFi One v. Broadcom*, Case Nos. 2015-1944, 1945, -1946 (Fed. Cir.) (*en banc*) (Argued May 5, 2017).

**Jeff B. Vockrodt***Partner*

Washington, DC

202.857.6311

jeff.vockrodt@arentfox.com

Jeff Vockrodt is a partner in Arent Fox's Intellectual Property group, where he focuses on global patent procurement and enforcement strategies, with an emphasis on chemical and pharmaceutical industries. He represents both patent owners and challengers in disputes involving a wide range of technologies, including semiconductors, medical devices, pharmaceuticals, biotechnology, and chemical processing. Jeff serves as lead counsel in inter partes review (IPR) proceedings before the Patent Trial and Appeal Board (PTAB), and has substantial experience throughout all aspects of ex parte and inter partes reexaminations in addition to interference proceedings before that tribunal including appeals to the Court of Appeals for the Federal Circuit (CAFC).

Jeff is a registered patent attorney with a chemical engineering background. He served for four years as patent examiner before the United States Patent and Trademark Office and a law clerk in the United States International Trade Commission Office of Unfair Import Investigations before entering private practice.

Client Work

Recent matters include:

- Preparing and prosecuting patent applications with an emphasis on ensuring adequate protection vis-à-vis the product under development and known competitive threats taking into account recent developments in patent jurisprudence.
- Preparing patent and market exclusivity defense strategies involving portfolio development to fend off challenges by way of Abbreviated New Drug Applications (ANDAs); 505(b)(2), or New Drug Applications related to competing products.
- Negotiate and counsel client as to license agreements including issues with respect scope, duration and patent term issues.
- Counsel clients as to all issues related to patent term including patent term adjustment (PTA) and patent term extension (PTE) including filing related petitions the Patent Office or challenges in District Court.
- Defend company's patent portfolio and respond to questions about the portfolio by parties conducting due diligence as part of a financing round or prospective merger.
- Conduct due diligence, freedom-to-operate, validity and patentability analyses, and prepare formal legal opinions of counsel as to third-party patents and in connection

Practices

Food, Drug, Medical Device & Agriculture

Intellectual Property

Life Sciences

Bar and Court Admissions

District of Columbia

District of Maryland

US Patent and Trademark Office

Education

The George Washington University Law School, JD

University of Arizona, BS (Chemical Engineering)

with transactions including providing an opinion of counsel to underwriters as to the company's patent issues in an initial public offering and subsequent financing rounds.

- As lead counsel to a global medical device company, obtained PTAB decision invalidating all challenged claims of a competitor's patents through IPR in a decision affirmed by the CAFC.
- Served as counsel in several IPR and CBM proceedings on behalf of the patent owner and challenger from pre-investigation, filing of the petition, litigation before the PTAB, and appeal to the CAFC.
- Represented patent owners and challengers in inter partes reexamination proceedings (the predecessor of IPR) many of which were litigation-related and included complex Patent Office petitions. One of the inter partes reexaminations Jeff handled was relied on by the Patent Office in its rulemaking related to the PTAB proceedings, Office Patent Trial Practice Guide, *In re Arviv*, Control No. 95/001,526 (Petition Decision April 18, 2011).
- Represented patent owners and petitioners in ex parte reexamination proceedings in cases related to pending or threatened litigation.
- Served as counsel before the Interference Trial Section on several interference proceedings to determine the party first to invent or resolve inventorship disputes among competing entities. issued with claims covering commercially important subject matter.

Publications & Presentations

Recent publications:

- Co-author, *Chemical & Life Sciences Year in Review* (2016)
- "PTAB Markush Rejection Practice and What it Means for Biotech Applicants," *Law360* (March 16, 2017)
- "3 Reasons Why Supreme Court Should Grant Cert in Critical Biotech Case" (April 26, 2016)
- "The Limitations and Advantage of IPR for Design Patents," *Law360* (April 12, 2016)
- Quoted Source "Three years after its passage, the AIA has brought IPRs and CBMs in front of the USPTO" *Inside Counsel Alphabet Soup*, Ed Silverstein (Sept. 1, 2015)
- Four Takeaways from the Federal Circuit's First Inter Partes Review Decision, *In Re Cuozzo*, *BNA Intellectual Property Technology and Law Journal* (February 9, 2015)

Recent presentations:

- Speaker, "Post-Grant Strategies: Inter Partes Review and Post-Grant Review," organized by Biomeridies and StartingBloch, Nimes, France (June 2015)
- Panelist, "Recent Trends in Patent Office Litigation before the Patent Trial and Appeal Board," Northern Virginia Technology Council, Tech Law and Procurement Committee Event (May 2015)
- Speaker, VIB (Flemish Biotech Institute)-US Patent One-Day Workshop, "Proceedings before the Patent Trial and Appeal Board" Sint-Martens-Latem, Belgium (November 2014)

**Alexander H. Spiegler**

Associate

New York, NY

212.457-5454

alexander.spiegler@arentfox.com

Alex Spiegler is a registered patent attorney whose practice focuses on all aspects of patent law. He has extensive experience with the US Patent & Trademark Office, specializing in patent prosecution and post-grant proceedings (e.g., *inter partes* reviews), in a wide variety of technologies, including biotechnology, agricultural technology, and pharmaceuticals. Alex also provides advice on claim construction, infringement and validity issues in litigation. Alex has been recognized by *Legal 500* as a leading lawyer in Patent Prosecution.

Client Work

Recent matters include:

- Preparing and prosecuting patent applications in the biotechnology, agricultural, pharmaceutical, and chemical arts, including inventions related to plants, herbicides, fertilizers, nucleic acids, proteins, antibodies, diagnostics, methods of treatment, and chemical processes.
- Conducting due diligence, freedom-to-operate, validity and patentability analyses in the biotechnology, agricultural, chemical and pharmaceutical arts, and prepare formal legal opinions reflecting conclusions of such analyses. Served as IP opinion counsel to pharmaceutical company in IPO.
- Represented agricultural company in *inter partes* review involving herbicidal compositions.
- Represented lawn care company in litigation and patent office proceedings. Successfully obtained summary judgment on competitor's trade secret claim. Obtained favorable *Markman* ruling against competitors' patents, leading to dismissal of the patent infringement suit. Successfully provoked *inter partes* reviews and reexaminations against competitors' patents, and obtained decisions that competitors' patents are unpatentable.
- Represented inventor against reexamination of patent directed to methods for treating achondroplasia. Reexamination Certificate confirmed patentability of all original claims.
- Represented agricultural biotechnology company against reexamination of patent directed to methods of treating genetically modified plant with an herbicide. Reexamination Certificate issued with claims covering commercially important subject matter.
- Represented life sciences company with patents

Practices

Food, Drug, Medical Device & Agriculture

Intellectual Property

Life Sciences

Bar and Court Admissions

District of Columbia

New York

Virginia

US Patent and Trademark Office

Education

Columbus School of Law at The Catholic University of America, JD

Rutgers University, BS (Biotechnology)

covering DNA sequencing technology. Obtained favorable *Markman* ruling.

- Represented life sciences company in patent office proceedings (interferences and reexaminations) relating to nucleic acid technology (e.g., sequencing, amplification). Represented life sciences company in patent office proceedings (interferences and reexaminations) relating to nucleic acid technology (e.g., sequencing, amplification).
- Represented pharmaceutical company in a Hatch-Waxman litigation brought against it by owner of patents covering leading attention hyperactivity disorder drug.

Publications & Presentations

Recent publications:

- Co-author, Chemical & Life Sciences Year in Review (2016)
- Co-author, “3 Reasons Why Supreme Court Should Grant Cert in Critical Biotech Case,” (April 26, 2016)
- Co-author, Pharmaceutical, Chemical and Biotech Year in Review (2013-2015)
- Co-author, Thinking Twice About “Comprising,” AIPLA’s *Biotech Buzz* (June 2015)
- Co-author, Inter Partes Review Year in Review (2014)
- Co-author, “Patent Reform Stalled by Tech and Pharma/ Biotech Debate,” *Daily Business Review* (2010)
- Co-author, “Recent Trends in Patent Practice: The Federal Circuit’s Treatment of Pharmaceuticals,” *BNA Life Sciences Law & Industry* (2007)

Recent presentations:

- “Latest Trends in US Patent Law Affecting the Life Sciences Industry,” Flanders Institute for Biotechnology, Gent, Belgium (2017)
- “Intellectual Property in the United States,” organized by StartingBloch, Nimes, France (2017)
- “Intellectual Property in the United States,” organized by StartingBloch, Montpellier, France (2016)
- “Intellectual Property in the United States,” organized by Biomeridies and StartingBloch, Nimes, France (2015)
- “Subject Matter Eligibility of Biotech and Pharmaceutical Inventions,” organized by Biomeridies and StartingBloch, Clapiers, France (2015)
- “Recent Developments in the Patent Office and Courts Affecting Life Sciences and Computer Patents in the United States,” Flanders Institute for Biotechnology U.S. Patent Seminar, Gent, Belgium (2014)
- “Developments in Biotechnology, Chemical and Pharmaceutical Law,” CLE Seminar, New York, NY (2012)
- “Legislative and Judicial Developments Affecting Patenting of Biotech Inventions in the United States,” DeClerq & Partners IP Seminar, Sint-Martens-Latem, Belgium (2011)

Chemical & Life Science Team Members



Richard J. Berman
Partner
Washington, DC
202.857.6232
richard.berman@arentfox.com



Janine A. Carlan
Partner
Washington, DC
202.857.6232
janine.carlan@arentfox.com



Jay R. Deshmukh
Partner
New York, NY
212.484.3979
jay.deshmukh@arentfox.com



Bradford C. Frese
Partner
Washington, DC
202.857.6496
bradford.frese@arentfox.com



Yelee Y. Kim
Partner
Washington, DC
202.857.6496
yelee.kim@arentfox.com



Richard LaCava
Partner
New York, NY
212.484.3958
richard.lacava@arentfox.com



Jeff B. Vockrodt
Partner
Washington, DC
202.857.6311
jeff.vockrodt@arentfox.com



Brian J. Malkin
Counsel
Washington, DC
202.857.6240
brian.malkin@arentfox.com



Anthony W. Shaw
Counsel
Washington, DC
202.857.6227
anthony.shaw@arentfox.com



Taniel E. Anderson
Associate
Washington, DC
202.857.6320
taniel.anderson@arentfox.com



Gary A. Coad
Associate
Washington, DC
202.857.6057
gary.coad@arentfox.com



Michael Scarpati
Associate
New York, NY
212.484.3917
michael.scarpati@arentfox.com



Alexander H. Spiegler
Associate
New York, NY
212.457.5454
alexander.spiegler@arentfox.com



Christopher H. Yaen
Associate
Washington, DC
202.350.3760
christopher.yaen@arentfox.com



Nicole Clarke
Patent Agent
Washington, DC
202.350.3680
nicole.clarke@arentfox.com



Jyoti Tibrewala
Patent Agent
Washington, DC
202.350.3742
jyoti.tibrewala@arentfox.com

Visit Us Online
arentfox.com/chemical-life-sciences

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Jeff B. Vockrodt

Partner

Washington, DC

202.857.6311

jeff.vockrodt@arentfox.com



Alexander H. Spiegler

Associate

New York, NY

212.457.5454

alexander.spiegler@arentfox.com



555 West Fifth Street, 48th Floor
Los Angeles, CA 90013
T 213.629.7400 F 213.629.7401

1675 Broadway
New York, NY 10019
T 212.484.3900 F 212.484.3990

55 Second Street, 21st Floor
San Francisco, CA 94105
T 415.757.5500 F 415.757.5501

1717 K Street, NW
Washington, DC 20006
T 202.857.6000 F 202.857.6395